Quality Manual

This manual has been written to comply with applicable requirements of the
ISO 9001:2008 and **ISO/TS 16949:2009**
International Quality Management System (QMS) Standards

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"We will achieve customer satisfaction by continually improving processes, products and services to ensure they consistently meet or exceed customer requirements".

Approval

Signature:	Name/Title:	Date:
_____	CEO	___/___/___
_____	ISO	___/___/___

0. Table of Contents

1. Scope

1.1 General

The automotive industry requires its supply base to participate in the design and development of the components and systems that compose an OEM vehicle. This shift in responsibility to the supply base for complete or partial responsibility for engineering, research, and development has been coined as Full Service Suppliers (FSS). IsoQual, Inc. has based the Quality Management System (QMS) described in this manual to demonstrate our FSS capability (see *Section 5.4.1.1*), to consistently provide products/services that meet customer and applicable regulatory requirements, and to operate with increased effectiveness and efficiency with the overall aim of enhancing customer satisfaction.

Our QMS utilizes the process approach and quality management principles contained in the international standards: *ISO 9000:2005*, *ISO/TS 16949:2009* and *ISO 9004:2009* to enhance our ability to continually improve. (Note: you must obtain a complete copy of the official versions of the latest *ISO* standards; use the links contained in this document, check with the accrediting body in your country, and/or contact *ISO* directly.)

Our QMS was also developed in accordance with the following four additional types of documents containing recommended automotive industry practices, examples, illustrations and explanations, to further facilitate continual improvement by emphasizing defect prevention and the reduction of variation and waste:

- International Automotive Task Force (IATF) Guidance to *ISO/TS 16949:2009*
- Quality System Assessment Checklist to *ISO/TS 16949:2009* (The "QSA Checklist" is obsolete as an IATF document, effective 1 June 2004 and is no longer available; however, you can utilize our QSA Checklist and Audit Guide as an internal audit tool, especially useful in conducting documentation reviews against the TS standard)
- *ISO/TS 16949:2009* Automotive Certification Scheme-Rules for Achieving IATF Recognition
- Customer-specific requirements and guidance documents

1.2 Application

Our QMS complies with all applicable requirements contained in *ISO/TS 16949:2009*, covers the design and provision of all company products, and encompasses all operations at our facility located at 1510 S. Pope Lick Road, Louisville, Kentucky, USA 40299 (?). The following table identifies *ISO/TS 16949:2009* requirements not applicable to our organization and provides a brief narrative justifying their exclusion from the scope of our QMS (exclusions are limited to clause 7.3, Product Design and Development only; note: clause 7.3 of *ISO/TS 16949:2009* always applies as applicable to Manufacturing Process Design and Development requirements):

ISO/TS 16949:2009 Requirements EXCLUSION TABLE

Clause or Sub-clause	Exclusion	Justification
	None	

2. Reference Documents. (list all documents actually referenced in your manual).

The following external documents contain provisions which, through reference in this manual, constitute provisions of our QMS:

ISO 9000:2005, Quality management systems – Fundamentals and vocabulary (Note: *ISO 9000:2000* was replaced with *ISO 9000:2005*. The latest version introduces no changes to the descriptions of the fundamentals of quality management systems; however, some definitions have been added including those for technical expert, requirement, competence, contract, auditor, audit team, audit plan, and audit scope.

ISO 9001:2008, Quality management systems – Requirements

ISO 9004:2009, Managing for the sustained success of an organization -- A quality management approach (Note: *ISO 9004:2000* was replaced with *ISO 9004:2009*. The latest version introduces no changes to the descriptions of the fundamentals of quality management systems; however, some definitions have been added including those for technical expert, requirement, competence, contract, auditor, audit team, audit plan, and audit scope.

ISO/TS 16949:2009, Quality management systems – particular requirements for the application of *ISO 9001:2008* for automotive production and relevant service part organizations

☐ Customer Specific Requirements (CSR) (list your unique CSR documents here):
- *???*

☐ Customer Reference Manuals (define your customer guidance documents here):
- *APQP*, Advanced Product Quality Planning & Control Plan (APQP)
- *FMEA-4*, Potential Failure Mode and Effects Analysis (FMEA Fourth Edition)
- *PPAP-4*, Production Part Approval Process (PPAP Fourth Edition)
- *SPC-3*, Statistical Process Control (SPC)
- *MSA-4*, Measurement Systems Analysis (MSA)
- *TS-QSA*, Quality System Assessment (QSA) Checklist. The "QSA Checklist" is obsolete as an IATF document, effective 1 June 2004 and is no longer available; we offer an adapted version of the QSA as an audit tool, see *Form 8.2.2-3*.
- CQI-8, Layered Process Audit (LPA) Guideline. Note: currently only applies as a GM Customer Specific Requirement
- International Automotive Oversight Bureau (IAOB) web site: (http://www.iatfglobaloversight.org/content.aspx contains a wide variety of resources including sanctioned interpretations and responses to frequently asked questions.

Appendix A contains a List of Key QMS documents referenced in this manual and defines the key top level processes for implementing our quality policy. Note: documents are referenced throughout this manual only by document number; see *Appendix A* for complete titles.

3. Terms and Definitions.

Our QMS uses the same internationally recognized terms, vocabulary and definitions given in *ISO 9000:2005* as supplemented by terms defined in *ISO/TS 16949:2009*, *Section 3.1*. Acronyms, terms, vocabulary and definitions unique to our organization, customers, industry and region and referenced throughout our QMS are contained in *Appendix B*, Terms and Definitions (define your unique terms/definitions, if any, in *Appendix B*).

4. Quality Management System

4.1 General requirements

Our QMS is that part of our overall management system which establishes, documents and implements our quality policy, and related processes for providing products and services which meet or exceed customer requirements, and satisfies QMS requirements of *ISO/TS 16949:2009*.

We have adopted the process approach advocated by *ISO 9000:2005*, by defining and managing:

- process inputs, controls, and outputs to ensure desired results are achieved, and
- interfaces between interrelated processes to ensure system effectiveness is achieved.

Our 'core' business processes are what we call 'Customer Oriented Processes', or COPs, which are in place to meet the specific needs of our external customers, which directly relate to requirements contained in Clause 7 of *ISO/TS 16949:2009*, Product Realization processes (i.e. things we 'do'). The basic sequence and interaction of our COPs is depicted in *COP 4.1*.

We have developed appropriate 'Support Oriented Processes', or SOPs, to help implement COPs in the most effective and efficient manner possible.

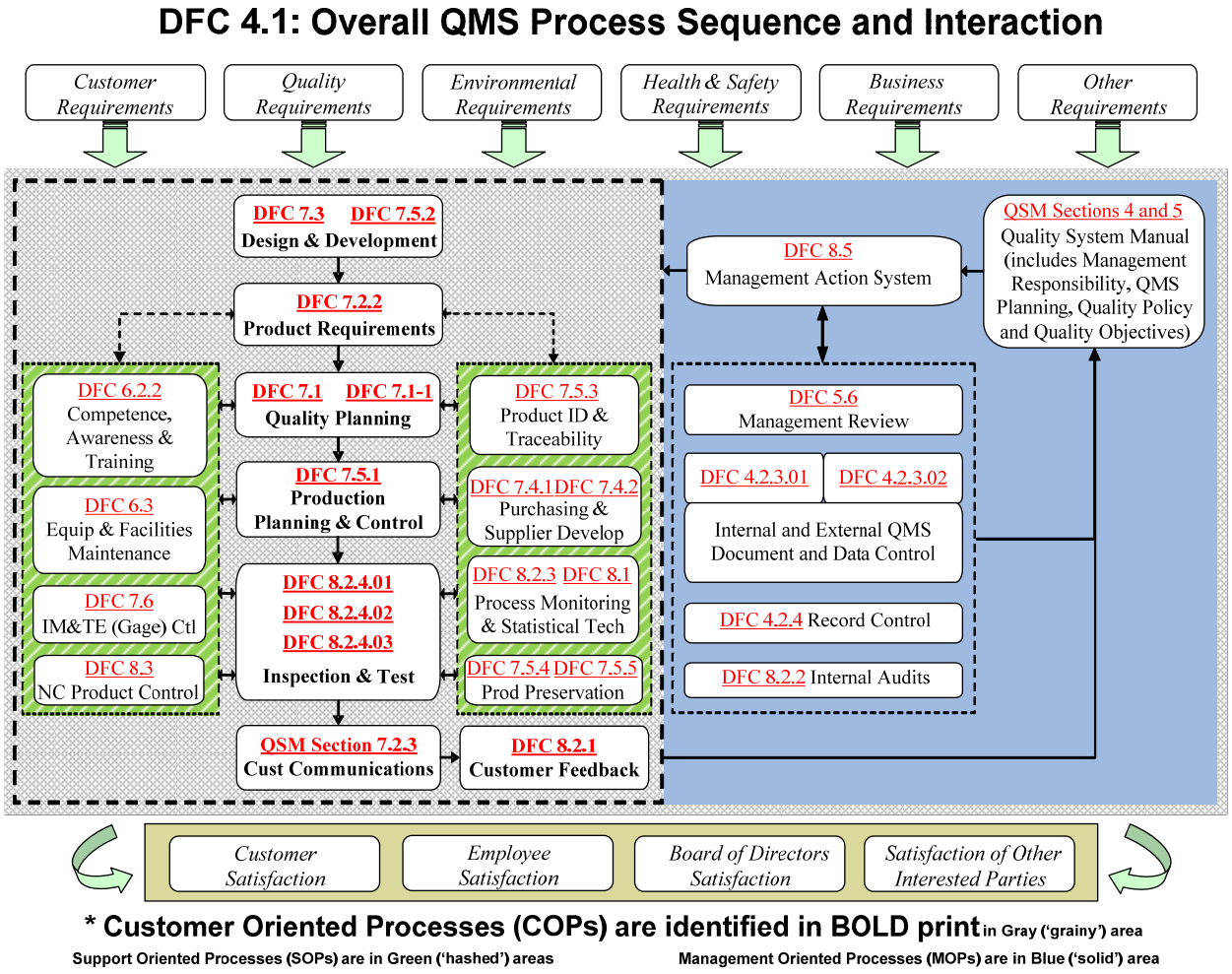
We also have developed 'Management Oriented Processes', or MOPs, to help meet the specific needs of management and our share holders, and/or to meet requirements of *ISO/TS 16949:2009* and other external standards and regulatory requirements.

The overall sequence of QMS processes (i.e. COPs, SOPs and MOPs) are depicted in *DFC 4.1* and their (primary) interaction is depicted in our COP Interaction Matrix, *WI 4.1-1*.

Techniques and tools for process management are discussed in *Section 8*.

Specific responsibilities for and the sequence and interaction of our key QMS processes are detailed in Operating Procedures (OPs), many of which contain or reference deployment flow charts depicting the process or procedure described in the narrative OP; *Appendix A* contains a List of Key QMS Documents, including all OPs and other key top level QMS documents.

4.1.1 *General requirements – Supplemental*. We also recognize the significant role that subcontractors play in achieving desired results and recognize that we must ensure proper control over outsourced QMS processes (*Section 7.4.1.2*). Outsourced processes are also depicted in both our *COP 4.1* and *DFC 4.1* flow charts; procedures governing their management are described in documents referenced in applicable OPs.



4.2 Documentation requirements

4.2.1 General

This manual contains documented statements of our quality policy and quality objectives and references documented procedures required by *ISO/TS 16949:2009* and other documents needed to ensure effective planning, operation and control of our key QMS processes (*DFC 4.1*).

The level and type of QMS documentation established for our business is continually reviewed to ensure it remains appropriate for the complexity and interaction of our processes and the competence of our employees. QMS documents and data may be in hard copy or electronic media. QMS documentation includes this quality manual, OPs, DFCs, and other internal and external documents and data needed to manage, perform or verify work affecting product quality.
We use OPs to document and define the key QMS processes depicted in *DFC 4.1*. We use DFCs and PAWs (with associated Turtle Diagrams) to aid in the development, assessment and/or improvement (*Section 8.4*) of processes defined in OPs. We also issue and control work instructions, job descriptions, and other internal and external documents and data as appropriate and needed to effectively manage our QMS (*Section 4.2.3*).

4.2.2 Quality manual

This manual is that part of our QMS that defines the scope of our QMS and documents the policy, procedures and processes needed to implement our quality policy and achieve our quality objectives. This manual also documents justifications for exclusions from *ISO/TS 16949:2009* requirements *(Section 1.2*) and defines the overall sequence of and interaction between our key QMS processes (*DFC 4.1*).

4.2.3 Control of documents

The ISO Management Representative (ISO) (?) has overall responsibility for ensuring that all QMS documents, including forms used to create quality records, are controlled per procedures detailed in *OP 4.2.3* and summarized below:

a) approve documents for adequacy prior to issue.
b) review, update as necessary and re-approve documents.
c) identify the current revision status of documents.
d) ensure that relevant versions of applicable documents are available at points of use.
e) ensure that documents remain legible, readily identifiable and retrievable.
f) ensure that documents of external origin (including customer engineering standards/specifications) are identified and their distribution controlled.
g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.3.1 *Engineering specifications.*

The Engineering Manager (ENG) (?) oversees our process for assuring the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on customer-required schedule; IsoQual, Inc. uses a Product Data Management (PDM) system to manage and control engineering records and data (see *OP 4.2.3*). Reviews are considered timely if performed within two working weeks of receipt. A change requires an updated record of customer production part approval when the specifications are referenced in the design record, or if the change affects Production Part Approval Process (PPAP) documents (*Section 7.3.6.3*).

4.2.3.1 *Master Lists*. Requirements for the establishment and maintenance of Master Lists of internal and external QMS documents are defined in *OP 4.2.3*.

4.2.4 Control of records

ISO (?) has overall responsibility for ensuring that all records required for the QMS (including customer-specified records) are controlled and maintained to provide evidence of conformance to requirements and effective operation of the QMS. Records are retained for a period defined by the customer, applicable regulatory requirements and/or IsoQual management, as applicable, and then disposed of in accordance with applicable requirements. Records may be in the form of hard copy or electronic media. *OP 4.2.4* details procedures necessary to control QMS records that, as a minimum, are prepared to document:

a) results of processes performed, including identification of the individual performing the activity.
b) product/process evaluation/acceptance criteria.
c) procedures, drawings or instructions used to perform an activity, including revision or date of document.
d) identification of material, parts, or equipment used in the making of the product.
e) personnel, material or equipment qualifications.
f) pertinent technical records from sub-contractors.

4.2.4.1 *Records retention*. *OP 4.2.4* contains related procedures and responsibilities to ensure:

- Record controls established satisfy all regulatory and customer requirements.
- Records controlled include customer-specified records.
- Disposition of records also includes their disposal.

5. Management Responsibility

5.1 Management commitment

Top Management (MGT) provides evidence of its commitment to the development, implementation and improvement of our QMS in very tangible ways:

Our quality policy statement (*Section 5.3*) documents and communicates the importance of meeting or exceeding all applicable requirements (including customer, regulatory and legal requirements) through continual improvement of our processes, products, and services.

We ensure that our quality policy is understood, implemented, and maintained at all levels of the organization through widespread printed distribution of our quality policy statement, and through periodic management review of the quality policy statement and corporate level improvement objectives (*Section 5.4*). In addition, our quality policy and objectives are communicated and deployed throughout the organization through individual performance objectives established and reviewed during employee performance reviews (*Section 6.2.2.4*).

All managers demonstrate their commitment to the development and improvement of the QMS through the provision of necessary resources (*Section 6.1*), through their involvement in the internal audit process (*Section 8.2.2*), and through their proactive involvement in our continual improvement activities (*Section 8.5.1*) – where emphasis is placed on improving both effectiveness and efficiency of our key QMS processes.

5.1.1 *Process efficiency.* MGT reviews product realization and support processes to assure both effectiveness and efficiency during management reviews (*Section 5.6.2*).

5.2 Customer focus

Our quality policy statement articulates our commitment to our customers:

> *We will achieve customer satisfaction by continually improving processes, products and services to ensure they consistently meet or exceed customer requirements*

MGT ensures a proper customer focus is established and maintained through the following activities:

Customer complaints and other customer input/feedback are continually monitored and measured to identify opportunities for improvement (*Section 8.2.1*).

We continually look for other ways to interact directly with individual customers to ensure a proper focus to their unique needs/expectations is established and maintained: e.g. customer audits, customer visits, trade shows, joint planning sessions, etc.

In addition, we have established a Customer Service Center and interactive web site: www.qualitymap.com (enter your web site here, if applicable) to provide customers with quick access to information and points of contact within our organization (*Section 7.2.3*).

These customer focused communications and interactions will yield clear, explicit customer requirements and expectations in the form of a contractual agreement or customer order; the Sales Manager (SM) (?) has overall responsibility for ensuring that specified and unspecified requirements are determined, understood, and converted into requirements (*Section 7.2*).

5.3 Quality policy

(insert your quality policy statement here):

We will achieve customer satisfaction by continually improving processes, products and services to ensure they consistently meet or exceed customer requirements

Our quality policy statement indicates our commitment and focuses on what is important to us as an organization: *achieving customer satisfaction*; and it prescribes the method by which we accomplish this: *by continually improving processes, products, and services to ensure they consistently meet or exceed requirements.* Moreover, our quality policy statement acts as a compass in providing the direction and a framework for establishing key corporate level performance measures and related improvement objectives (*Section 5.4.1*).

We ensure that our quality policy is communicated and understood at all levels of the organization through documented training, regular communication, and reinforcement during annual employee performance reviews (*Section 6.2.2.4*).

Our quality policy statement is controlled by inclusion in this manual, and along with all policies contained in this manual, is reviewed for continuing suitability during management review meetings (*Section 5.6.2*).

5.4 Planning

5.4.1 Quality objectives

Our overall quality goal is to achieve our quality policy, and maintain the integrity of and continually improve a QMS compliant with *ISO/TS 16949:2009*. Further, we establish both corporate level and operational level improvement objectives that are measurable and achievable within a defined time period. Corporate level improvement objectives, derived from our Business Plan and customer goals/targets, are documented on a Continual Improvement Form, *Form 8.5-6*, and reviewed for achievement during management reviews (*Section 5.6.2*). All managers (?) of key QMS processes monitor and measure performance of processes within their area(s) of responsibility and, where appropriate, establish measurable operational level improvement objectives consistent with our quality policy and corporate level improvement objectives. Operational level improvement objectives are documented on Process Assessment Worksheets (PAWs), *Form 8.4-1*, and deployed to individuals or individual work areas and monitored for achievement through employee performance reviews (*Section 6.2.2.4*).

Corporate and operational level improvement objectives will be reviewed for consistency, accomplishment and clarity through our management review process (*Section 5.6*) and may include any/all of the following possible measures: (list here areas where you will eventually establish measurable quality objectives, probably should include all of the following):

- Customer Satisfaction: SLS (?); *Section 8.2.1*.
- Supplier Performance: Materials Manager (MAT) (?); *Section 7.4.1.2*.
- QMS Effectiveness: ISO Management Representative (ISO) (?);*Section 8.5.1*.
- Overall Operational Efficiency and Manufacturing Process Efficiency: Chief Financial Officer (CFO) (?); with input from the Production Manager (PRO); *Section 6.1* and *Section 5.1.1*.
- Training Effectiveness and Employee Awareness: Human Resources Officer (HRO) with input from the Training Manager (TM) (?); *Section 6.2.2.4*.
- Product Performance: ENG (?); *Section 7.3*.
- Effectiveness of Manufacturing Processes: PRO (?); *Section 7.5.1*.
- Product Quality: Quality Manager (QM) (?); *Section 8.2.4*.

5.4.1.1 *Quality objectives – Supplemental*. MGT utilizes the management review process (*Section 5.6.2*) to define quality objectives and measurements to be included in our Business Plan and used to deploy our quality policy. Specific measurable objectives adopted will be based on achievable performance within a specified time frame, driven by the following objectives we strive to achieve as a Full Service Supplier (FSS) to the automotive industry:

a) Achievement of ZERO DEFECTS (*Section 8.2.3.1*) and 100% on time delivery (*Section 7.5.1.6*) performance.

b) Manage and control facilities, processes, quality systems and personnel to consistently and cost effectively produce products and furnish services that meet customer needs (*Section 7.5.1*).

c) Develop and implement Advanced Product Quality Planning (*APQP*) practices and procedures (*Section 7.1.1*) in accordance with *ISO/TS 16949:2009*, including the AIAG "Advanced Product Quality Planning and Control Plan" reference manual, *APQP*, and associated customer specific requirements documents.

d) Provide objective evidence that all supplied products and services satisfy all AIAG Production Part Approval Process (PPAP) requirements, *PPAP-4*, (*Section 7.3.6.3*) as required including acceptable process capabilities for all Special/Control Characteristics that have been established. Note: In the absence of any specific instructions, we will default to a level 3 PPAP submission (*Section 7.1.1*).

e) Utilize appropriate statistical techniques for on-going process control and improvement (*Section 8.1*) as established in the AIAG "Statistical Process Control (SPC)" reference manual, *SPC-3* , and associated customer specific requirements documents.

f) Be committed to continuous process improvement (*Section 8.5.1.2*) by emphasising reduction of part-to-part variation and the elimination of all waste.

g) Conduct operations in conformance with, or to exceed, all applicable environmental laws and regulations of the jurisdictions in which we do business (*Section 6.4*).

h) Meet customer requirements with regard to use, control and supply of returnable packaging (*Section 7.5.5*).

5.4.2 Quality management system planning

The QMS planning process involves the establishment and communication of our quality policy (*Section 5.3*) and objectives (*Section 5.4.1*) through issuance of this manual and its associated procedures, and through the provision of resources needed for its effective implementation (*Section 6.1*). Accordingly, this manual constitutes our overall plan for establishing, maintaining and improving an effective QMS. Our management review process (*Section 5.6*) and internal audit process (*Section 8.2.2*) ensure the integrity of our QMS is maintained when significant changes are planned and implemented that affect our key QMS processes depicted in *DFC 4.1*.

The QM (?) develops appropriate quality planning documents for specific products, projects or contracts whenever customer requirements exceed the capability or intent of the product/service realization and support processes described in our QMS (*Section 7.1*).

5.5 Responsibility, authority and communication

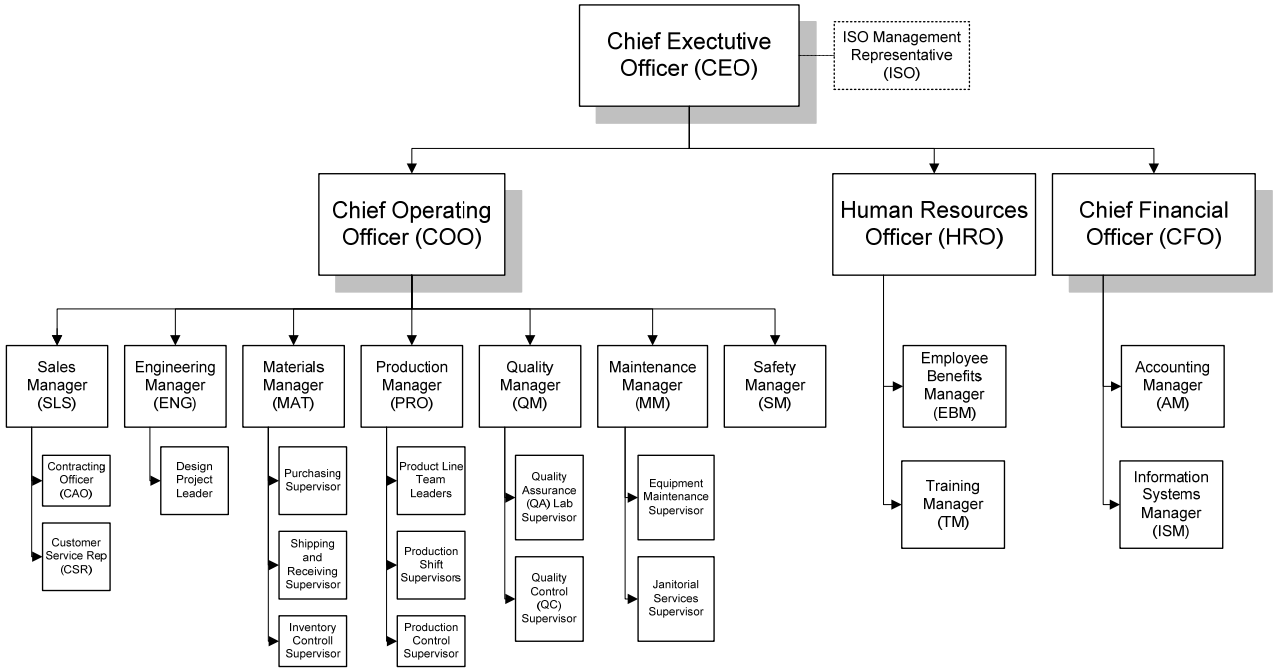
5.5.1 Responsibility and authority

The Chief Executive Officer (CEO) sets direction and ensures the success of our business through the clear definition and communication of QMS responsibilities and authorities. Other members of Top Management (MGT) include: (?) the Chief Operations Officer (COO), the Chief Financial Officer (CFO) and the Human Resources Officer (HRO). The interrelationship of MGT and other key personnel is depicted our Organization Chart, *Form 5.5.1.*

Responsibility and interaction of QMS processes is also depicted in *DFC 4.1*, *COP 4.1*, *WI 4.1-1*.

Organization Chart

Form 5.5.1
Rev: 0 12/31/10



5.5.1.1 *Responsibility for quality*. Overall QMS responsibility and authority is summarized in our Responsibility Matrix, *Form 5.5.2*, and in the following paragraphs (summarize here):

- Top Management (MGT) – Members of MGT are ultimately responsible for the quality of IsoQual's products and services since they control the systems and processes by which work is accomplished. MGT is responsible for Business Planning, development and communication of our quality policy (*Section 5.3*), QMS Planning (*Section 5.4.2*) including the establishment and deployment of objectives (*Section 5.4.1*), the provision of resources needed to implement and improve the QMS (*Section 6.1*) and management reviews (*Section 5.6*).

- Management – All managers are responsible for execution of the Business Plan and implementation of the policy, processes and systems described in this manual. All managers are responsible for planning and controlling QMS processes within their area(s) of responsibility, including the establishment and deployment of operational level objectives (*Section 5.4.1.1*), and the provision of resources needed to implement and improve these processes (*Section 6.1*). Managers also conduct employee performance reviews (*Section 6.2.2.4*). Management with responsibility and authority for corrective action are notified promptly of non-conformities (*Section 8.5.2*). Management ensures that production across all shifts are staffed with personnel in charge of, or delegated responsibility for product quality (*Section 7.5.1.1*).

- Employees - All employees are responsible for the quality of their work and

implementation of the policy and procedures applicable to processes they perform (*Section 8.2.3*). Personnel responsible for product quality have the authority to stop production to correct quality problems (*Section 8.3*). Employees are motivated and empowered (*Section 6.2.2.4*) to identify and report any known or potential problems and recommend related solutions through internal audits (*Section 8.2.2*) and/or the continual improvement and corrective/preventive action processes (*Section 8.5*).

Detailed responsibilities and authorities for QMS implementation and improvement are contained in lower level documents referenced throughout this manual and other QMS documents including procedures, flow charts, job descriptions, work instructions, etc.

5.5.2 Management representative

ISO (?) is appointed as IsoQual's management representative with delegated responsibilities for ensuring that an *ISO/TS 16949:2009* compliant QMS is established, implemented, and maintained; for promoting awareness of customer requirements throughout the organization (*Section 5.5.3*); and for ensuring that the performance of the QMS is reviewed by MGT for effectiveness, continuing suitability and the need for improvement (*Section 5.6*).

5.5.2.1 *Customer representative*. A list of Customer Service Representatives (CSR), with responsibility and authority for ensuring that customer requirements are adequately addressed throughout our organization, can be found on our web site (?) at www.qualitymap.com (?).

5.5.3 Internal communication

We communicate information regarding QMS processes and their effectiveness through documented training (*Section 6.2.2*), the internal audit process (*Section 8.2.2*), continual improvement and corrective/preventive action processes (*Section 8.5*), and regular formal and informal communications as follows (identify your communication systems here):

- ISO (?) posts information on quality bulletin boards throughout the facility to convey information regarding customer requirements, and the status and importance of quality activities. Internal audits (*Section 8.2.2*) are also used to reinforce or communicate appropriate information to employees.

- The SM (?) posts information on safety bulletin boards throughout the facility to convey information regarding the status of the Safety and Environmental Management Program, and related statutory/regulatory requirements.

- The HRO (?) posts information on employee bulletin boards throughout the facility to convey information regarding employee benefits, programs, involvement opportunities, and applicable statutory/regulatory requirements. The HRO (?) is also responsible for publication of IsoQual, Inc.'s newsletter, *ISO-ONLINE* (identify your newsletter title here, if applicable).

- The ISM (?) ensures that consistent and effective formal communication is facilitated through our Intranet system and interactive web site: www.qualitymap.com (identify

your web site here, if applicable).

All officers, managers and supervisors (?), are responsible for establishing internal communications as needed to convey to their employees the relevance and importance of their activities; typically this information is conveyed through production team meetings and cross-functional improvement projects (*Section 8.5.1*) (identify your communication mechanisms here). Communications regarding how employees contribute to the achievement of objectives is also conveyed and reinforced during employee performance reviews (*Section 6.2.2.4*).

5.6 Management review

5.6.1 General

The CEO has overall responsibility for conducting a management review meeting at least once annually to ensure the continuing suitability, adequacy, and effectiveness of our QMS in accordance with procedures detailed in *OP 5.6*. The primary inputs reviewed include data that measures the conformance and performance of our QMS. Conformance is primarily assured through internal audits (*Section 8.2.2*) and demonstrated through a review of internal audit results and our demonstrated ability to correct/prevent problems. Performance is primarily assured through the deployment of corporate/operational level objectives (*Section 5.4.1*) and demonstrated through a review of our demonstrated ability to achieve desired results. The primary output of management review meetings are management actions taken (*Section 8.5*) to make changes or improvements to our QMS and the provision of related resources.

5.6.1.1 *Quality management system performance*. Each management review includes all requirements of the QMS and its performance trends, including monitoring of quality objectives (*Section 5.4.1*), regular evaluation of the cost of poor quality (*Section 8.4*) , and an assessment of the suitability and effective of support processes (i.e. plant, facility and equipment, *Section 6.3.1*) as an essential part of our continual improvement process (*Section 8.5.1*). At a minimum, these results are used to demonstrate achievement of the quality objectives in our Business Plan and customer satisfaction with supplied product.

5.6.2 Review input

The management review meeting includes a review of our quality policy (*Section 5.3*), all applicable requirements of the QMS, related performance trends and opportunities for improvement, follow-up actions from earlier management reviews, results of self assessments (*Section 8.4*), and strategic or operational changes that could affect the QMS.

At a minimum, corporate level effectiveness and/or efficiency improvement objectives (*Section 5.4.1*) documented in prior management reviews (and/or specified in our Business Plan) are reviewed for status and continuing suitability:

5.6.2.1 *Review input – Supplemental*. In addition, The ENG (?) provides an analysis of actual and potential field-failures and their impact on quality, safety or the environment as an input to the management review process.

5.6.3 Review output

At a minimum, outputs from management review meetings include new/revised corporate level improvement objectives and any related actions required for improvement of the QMS and its processes, improvement of product related to customer requirements, and provision of resource needs. Results of management review meetings are recorded and maintained by ISO (?) per *OP 5.6*.

6. Resource Management

6.1 Provision of resources

The CFO (?), with input from all responsible managers, ensures, appropriate resources, including trained employees and appropriate equipment, facilities, support services and work environment needed to implement, manage and improve an effective/efficient QMS and enhance customer satisfaction, are identified and provided through our budgeting and other business management processes including but not limited to:

Section 5.4.2, QMS Planning
Section 5.5.1.1, Business Planning (responsibility for quality)
Section 6.2.2, Human Resource Planning
Section 6.3.1, Plant, Facility, Equipment and other Infrastructure Planning
Section 6.3.2, Contingency Planning
Section 6.4, Work Environment and Safety Planning
Section 7.1, Product Quality Planning (including Advance Product Quality Planning)
Section 7.2, Planning of Customer-related Processes
Section 7.3.1, Product and Manufacturing Process Design and Development Planning
Section 7.4, Planning of Purchased Product (Materials, Services and Vendors)
Section 7.5.1, Production and Service Provision Planning
Section 7.6, Measurement Systems Planning (including the conduct of MSA)
Section 8.1, Measurement, Analysis and Improvement Planning (including the use of SPC)
Section 8.5.1.1, Organizational Continual Improvement Planning
Section 8.5.1.2, Manufacturing Process Continual Improvement Planning

The CFO (?), with input from other responsible managers, monitors and measures overall operational efficiency (including the cost of poor quality) and provides related input and recommendations that may affect QMS effectiveness to MGT for review and action (*Section 5.6*).

6.2 Human resources

6.2.1 General

We believe that our employees are our most valuable resource and we do our best to help them achieve their full potential through continual education and training.

6.2.2 Competence, awareness and training.

The competency of people assigned responsibilities defined in the QMS is determined on the basis of documented criteria for appropriate education, training, skills, and experience for each required competency or work assignment. The HRO (?) has overall responsibility for administering IsoQual's Human Resource Management programs in accordance with procedures detailed in *OP 6.2.2* and the following policies.

6.2.2.a *Need Determination.* We determine competency needs, including employee training and awareness needs, through the following actions:

MGT identifies emerging competency needs during business planning and reports/evaluates their impact during management reviews (*Section 5.6*). Emergent competency needs are converted into job descriptions for the type and number of positions that need to be filled through external recruitment, internal reassignment/promotion, and/or outsourcing actions.

The HRO, (?), with input from responsible managers, evaluates and qualifies applicants for specific job openings on the basis of documented or demonstrated competencies. Where possible, we help existing employees qualify for new/changed jobs through the provision of appropriate education and training, including on-the-job-training (OJT).

The HRO (?), with input from responsible managers, establishes and maintains job descriptions for each position held at IsoQual to document the specific competencies needed to ensure the quality of IsoQual's products and services. At a minimum, these include:

6.2.2.1 *Product design skills*. The ENG (?) ensures that personnel with product or manufacturing process design responsibility (*Section 7.3.1.1)*are competent to achieve design requirements and are skilled in design methods (*Section 7.3.3*) needed to achieve desired results.

6.2.2.2 *Training*. Responsible managers (?) identify training needs for their employees and achieve competence of all personnel performing activities affecting product quality. Personnel performing specific assigned tasks are qualified, as required, with particular attention to the satisfaction of customer requirements (application of digitized mathematically based data, e.g.).

6.2.2.3 *Training on the job*. Responsible managers (?) ensure on the job training (OJT) is provided for personnel in any new or modified job affecting product quality, including agency or contract employees. Responsible managers (?), through the employee performance review process, also ensure that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of our objectives.

6.2.2.4 *Employee motivation and empowerment*. We utilize the employee performance review process to motivate employees to achieve individual or functional performance objectives that support achievement of our corporate objectives (*Section 5.4.1*). Employee performance reviews and the internal audit process (*Section 8.2.2*) are used to promote and assess the extent of quality and technological awareness throughout our organization. Responsible managers, officers and supervisors (?) re-evaluate employee competencies and evaluate employee performance against established objectives through our employee performance review process.

6.2.2.b *Provision.* Training needs identified as a result of the need determination activities discussed above are passed on to the TM (?) for appropriate planning and timely provision.

6.2.2.c *Effectiveness.* We evaluate the effectiveness of all actions taken to meet competency needs. Training provided is evaluated through immediate feedback from the employee and the manager, officer, or supervisor who identified the training requirement. Training effectiveness is collected and documented by the responsible manager for each training event. The HRO (?), with input from the TM and other responsible managers, monitors and measures the overall effectiveness of training and other actions taken to meet competency needs and provides related recommendations to MGT for review and action (*Section 5.6*).

6.2.2.d *Employee Awareness.* We ensure that our employees are aware of customer requirements (*Section 5.5.2* and *Section 5.5.2.1*), the relevance and importance of their activities and how they contribute to the achievement of our quality policy (*Section 5.3*) and objectives (*Section 5.4.1.1*). This is accomplished through awareness training (see employee overview and executive overview), employee performance reviews (*Section 6.2.2.4*), and employee participation in our internal audit (*Section 8.2.2*) and improvement (*Section 8.5*) processes.

6.2.2.e *Records.*. We maintain appropriate records of education, training, skills and experience in accordance with provision of *Section 4.2.4*. Employee qualification/competency review records and annual performance review results are maintained by the HRO (?). The TM (?) maintains records of all training completed.

6.3 Infrastructure

The COO (?) has overall responsibility for planning, providing and maintaining the resources needed to achieve product conformance, including buildings, workspace and associated utilities; process equipment (hardware and software); and supporting services (such as internal transportation and material handling systems and communications systems).

The MM (?) has overall responsibility for managing our Facilities and Equipment Maintenance programs in accordance with *OP 6.3*; these programs include:

- facilities management, maintenance and repair
- housekeeping/custodial services management
- process equipment management, maintenance and repair
- production tooling management, and
- transportation and material handling equipment management, maintenance and repair.

6.3.1 *Plant, facility, and equipment planning*. The COO (?) uses a multidisciplinary approach for developing plant, facility and equipment plans. The ENG (?) ensures plant layouts are designed and continually evaluated through the application of lean manufacturing principles (state your approach here) to minimize material travel, handling and value-added use of floor space and facilitate synchronous material flow. The MM (?) develops and implements an effective preventive maintenance program utilizing predictive maintenance methods (*Section 7.5.1.4*) as appropriate. The ISM (?) has overall responsibility for managing our automated data processing and communications systems. The effectiveness of these efforts is reviewed during management reviews (*Section 5.6.1.1*).

6.3.2 *Contingency plans*. The COO (?), in conjunction with the ENG, MM, PRO, QM, SM, ISM (?) and other appropriate managers, ensures contingency plans are documented (in the Business Plan?) and implemented as needed to satisfy customer requirements in the event of an emergency such as utility interruptions, labor shortages, key equipment failure and field returns.

6.4 Work environment

We provide employee benefits, job and schedule flexibility, interesting work, and involvement of our employees in an empowered environment of continual improvement (*Section 6.2.2.4*). We engender total participation by involving employees in internal audit (*Section 8.2.2*) and improvement (*Section 8.5*) activities. The HRO (?) has overall responsibility for identifying, implementing and maintaining effective employee benefit and workforce involvement programs.

The Safety Manager (SM) (?) has overall responsibility for identifying, implementing and maintaining safety and environmental management systems, processes and controls needed to ensure product conformance and meet customer, statutory or regulatory requirements; (reference applicable Safety and/or Environmental Management documents). We monitor and improve workplace safety, health, and ergonomics through adherence to good manufacturing practices, and through safety team meetings and training (*Section 6.2.2*).

6.4.1 *Personnel safety to achieve product quality*. We design and carry out production processes to ensure product safety and minimize potential risks to employees as may be identified during development of design FMEAs (*Section 7.3.3.1*) and/or process FMEAs (*Section 7.3.3.2*) and documented in work instructions located in process areas (*Section 7.5.1.2*).

6.4.2 *Cleanliness of premises*. We provide and maintain a work environment in a state of order, cleanliness and repair consistent with the product and manufacturing process needs (*Section 6.3*)

7. Product Realization

7.1 Planning of product realization

Our QMS identifies, plans for and documents our product and service realization processes to ensure consistency with all applicable requirements, including customer requirements and related quality objectives and requirements for specific products/services, and any/all applicable statutory/legal requirements. The outputs of product/service realization planning include the specific methods, facilities, equipment, people and materials/support services needed to achieve all desired results for a particular product, service, or contract. Essentially, the outputs of the quality planning process applicable to all products/services are the traveler, work instructions and other data in job packs (*Section 7.5.1.2*) or located in work areas where needed.

When requirements are not adequately addressed in the standard job pack documentation/data, or as required by the customer, the QM (?) has overall responsibility for developing and implementing a quality control plan to address additional requirements or controls needed to verify work for the specific process, product or contract in question; see *OP 7.1*.

The outputs of quality planning (i.e. job packs, control plans, etc.) are carried out in accordance with planned monitoring and measurement activities (*Section 8.2*), which may also include the use of appropriate statistical techniques (*Section 8.1*).

7.1.1 Planning of product realization – Supplemental. Customer requirements and references to its technical specifications are included in the planning of product realization as a component of the quality plan. Our automotive customers refer to Advanced Product Quality Planning (*APQP*) as the means to achieve product realization. APQP embodies the concepts of error prevention and continual improvement as contrasted with error detection and is based on a multidisciplinary approach. IsoQual, Inc. applies the requirements of product and manufacturing process design (*Section 7.3*) to development of product realization processes through our APQP process.

7.1.1.1 Our APQP/PPAP process, as detailed in *OP 7.1*, and depicted in *DFC 7.1-1*, provides a consistent advanced product quality planning process acceptable to all of our automotive customers, *APQP*. The APQP Team Leader (?) establishes an APQP Team and serves as the APQP contact with the customer throughout the launch. The APQP process is used by the APQP Team to:

- Develop/finalize special characteristics.
- Develop/review failure modes and effects analysis
- Establish actions to reduce potential failure modes with high risk
- Develop/review control plan
- Report and timely provision of required deliverables (i.e. Tooling, Fixtures, PFMEA, Control Plans, PPAP, Run @ Rate, etc.)
- Develop/review lessons learned during Technical Reviews, APQP Kick-Off Meetings and all Program Reviews.

7.1.1.2 *Special Characteristics* for inclusion in the control plan comply with customer specified definitions and symbols and other process control documents (including drawings, FMEAs, operator instructions, etc.) that affect product characteristics and process parameters.

7.1.1.3 *Production Part Approval Process (PPAP)* (*Section 7.3.6.3*). The APQP Team Leader (?) implements a production part approval process recognized by our customers, *PPAP-4*; see *OP 7.1*) and *DFC 7.1-1*; in the absence of any specific instructions, we will default to a level 3 PPAP submission. PPAP approval is obtained prior to the first production shipment of product (unless specifically waived by the customer); the APQP Team Leader (?):

- Ensures submissions for part approval are prior to the implementation of the change, to determine the type of quality re-certification required (PPAP documentation.)
- Product modified by an engineering change to design records, specifications, or materials.
- Use of another optional construction or material than originally approved.
- Production from new or modified tools (except perishable tools), dies, molds, patterns, etc., including additional or replacement tooling. (Partial or complete)
- Production following refurbishment or rearrangement of existing tooling or equipment.
- Production following any change in process or method of manufacture.
- Production from tooling and equipment transferred to a different plant location or from an additional plant location.
- Change of source for subcontracted parts, materials, or services (e.g. heat treating or plating)
- Product re-released after the tooling has been inactive from volume production for twelve months or more.
- Following a customer request to suspend shipment due to a supplier quality concern.

7.1.2 *Acceptance criteria*. Acceptance criteria is approved by the customer, where required. For attribute data sampling, the acceptance level is zero defects (*Section 8.2.3.1*).

7.1.3 *Confidentiality*. We ensure the confidentiality of customer-contracted products and projects under development and related product information (*Section 7.5.4*).

7.1.4 *Change control*. The QM (?) obtains necessary customer approval of quality plans, acceptance criteria, product and/or manufacturing process, and all related changes that may impact product realization. For propriety designs, impact of form, fit and function (including performance and durability) are reviewed with the customer so all effects can be properly evaluated (*Section 7.3.7* and *OP 7.1*). When required by the customer, additional verification and identification requirements is performed, such as required for new product introduction and validation (*Section 7.3.6*) and *OP 7.1*).

7.2 Customer-related processes

Achieving our quality policy "to meet or exceed customer requirements" requires that we determine, understand, and consistently meet or exceed our customers' requirements and expectations, and that we establish effective communication systems with our customers with regards to product information, inquiries, contract or order handling and related changes, and customer feedback, including complaints. These efforts are described below. SLS (?) has overall responsibility for developing and implementing effective customer-related processes in accordance with the policies in this section and *Section 8.2.1*.

7.2.1 Determination of requirements related to the product

Sales personnel (?) generate quotes/bids and negotiate final contracts/orders; Customer Service personnel (?) receive customer orders for standard (catalog) items or for items included previously bid or negotiated. Requirements for most major customers are identified in contracts documented and reviewed annually. In other cases, a customer order constitutes a contract, and we ensure that the customer's requirements are clearly identified and confirmed prior to acceptance. *OP 7.2.2* defines our process for determining product related requirements:

7.2.1.1 *Customer-designated special characteristics*. This includes customer requirements for designation, documentation, and control of special characteristics (*Section 7.3.2.3*).

7.2.1.2 Product requirements specified by the customer, including the requirements for availability, delivery and support including any after-sales product service and/or post-delivery servicing (*Section 7.5.1.8*) provided as part of the customer contract or purchase order.

7.2.1.3 Product requirements not specified by the customer but necessary for intended or specified use and obligations related to product, including regulatory and legal requirements; this may include recycling, environmental impact, and characteristics identified as a result of IsoQual's knowledge of the product and related production processes.

7.2.1.4 All applicable government, safety, and environmental regulations applied to the acquisition, storage, handling, recycling, elimination or disposal of materials.

7.2.2 Review of requirements related to the product

Sales or Customer Service personnel (?) review customer requirements identified during the determination process (*Section 7.2.1*) to ensure that they are clearly stated, understood, and recorded. Our process for reviewing all applicable requirements is defined in *OP 7.2.2* to ensure:

- all applicable product requirements are defined, understood and confirmed with the customer prior to acceptance
- manufacturing feasibility of proposed (new or changed) products is investigated, confirmed and documented prior to making a commitment to supply
- contract or order requirements differing from those previously expressed are resolved
- records of the review and actions resulting from the review are maintained (*Section 4.2.4*)

7.2.2.1 *Review of requirements related to the product – Supplemental*. SLS (?) obtains necessary customer authorizations to waive formal reviews where it is deemed impractical for each order.

7.2.2.2 *Organization manufacturing feasibility*. The ENG (?) investigates, confirms and documents the manufacturing feasibility of proposed automotive products, including risk analysis, and product design input (*Section 7.3.2.1*) and manufacturing process design input (*Section 7.3.2.2*) in accordance with customer-specific requirements governing the APQP/PPAP process detailed in *OP 7.1* and depicted in *DFC 7.1-1*, in accordance with *APQP*, (*Section 7.1.1*) (reference your customer-specific documents here).

Where product requirements are changed, we ensure relevant documents are amended and relevant personnel are made aware of the changed requirements; see *OP 7.2.2*.

7.2.3 Customer communication

Customers will be provided information for the following 'key' customer contact personnel: Buyer, Quality Engineer / APQP Team Leader, Design Engineer / Design Project Team Leader.

Customers will also be provided points of contact the following key functions: Manufacturing / Production, Materials Management / Logistics, Purchasing, APQP Team Leader.

Customer communications are established through a variety of channels:

- Sales and Customer Service personnel (?) provide *product information* directly to customers including verbal and printed information on our standard product offerings as well as customized information for unique customer applications.

- *Inquiries* are handled by our Sales or Customer Service personnel (?) depending on the nature of the inquiry or who made initial contact; *Section 7.2.1*. Engineering personnel (?) provide *technical assistance* and related information as needed.

- We pay particular attention to customer feedback, including *customer complaints* and customer satisfaction. We have a toll-free number and a wide sales network to encourage and address customer feedback, particularly customer complaints. *Customer satisfaction* is evaluated on an on-going basis by customer contact personnel, i.e. Sales and Customer Service personnel (?); see *Section 8.2.1*.

- Our ISM (?) maintains a user/customer friendly web site, www.qualitymap.com (enter your web site here, if applicable) which contains extensive product information, a list of contacts of use to both customers and suppliers, and an electronic customer feedback form.

7.2.3.1 *Customer communication – Supplemental*. The ISM (?) establishes/maintains an ability to communicate necessary information, including data, in a customer specified language and format, including but not limited to computer-aided design (CAS) data and electronic data interchange (EDI).

7.2.3.1.1 Electronic Data Interchange (EDI)

IsoQual, Inc. believes that the most effective and efficient way to communicate throughout our supply chain is to utilize a common industry practice for EDI. IsoQual, Inc. and our automotive customers require EDI methods to be employed by all partner suppliers throughout the supply chain. All of our EDI initiatives, policies, and transaction sets comply with the guidelines set forth by the AIAG and our key suppliers are also mandated to have the capability to interface with us electronically. Any updates, new releases, system changes, etc. are communicated to our key suppliers by the ISM (?).

7.2.3.1.2 Advanced Shipping Notice (ASN)

An ASN is the electronic transfer of shipping data to the customer (*Section 7.5.5.2*).

7.3 Design and development.

Design and development processes are employed at IsoQual to transform customer requirements into specifications, products, processes or systems. The ENG (?) maintains a list of products/services for which IsoQual, Inc. has design responsibility, i.e. the authority to establish a new, or change an existing, product specification; this responsibility includes testing and verification of design performance within customer specified applications. The ENG (?) has overall responsibility for managing product design and development activities in accordance with *OP 7.3*. and serves as the overall Product Design Team Leader (as referenced throughout this section) The ENG (?) with assistance from the QM has overall responsibility for managing manufacturing process design and development activities (for automotive products) in accordance with our APQP/PPAP process detailed in *OP 7.1* and depicted in *DFC 7.1-1* in accordance with customer specific requirements (see *APQP* and *Section 7.1.1*); and serves as the overall APQP Team Leader (as referenced throughout this section).

7.3.1 Design planning

The ENG (?) assigns a qualified Design Engineer to serve as Design Team Leader (?) for design projects for new/changed non-automotive products; The QM (?) assigns a qualified Quality Engineer to service as APQP Team Leader (?) for design projects involving new/changed automotive products and related manufacturing processes. The Design (or APQP) Team Leader (?) utilizes project management planning tools (available software etc.) to establish a Design Plan that, at a minimum, identifies design stages, predetermined design reviews, scheduled verification and validation activities. Design plans are retained in a Design Folder.

7.3.1.1 *Multidisciplinary approach*. The Design (or APQP) Team Leader (?) forms a Design (or APQP) Team composed of design, manufacturing, engineering, quality, production and other appropriate qualified personnel to prepare for product realization, through:

- development/finalization and monitoring of special characteristics
- development and review of Potential Failure Mode Effects Analysis (FMEA) including actions to reduce potential risks per customer guidance, *FMEA-4*, and requirements
- development and review of control plans

7.3.2 Design inputs. The Design (or APQP) Team Leader (?) identifies, documents (*Section 4.2.4*) and reviews *design inputs*; and, before finalizing documentation of required inputs, resolves any incomplete, ambiguous or conflicting requirements (*Section 7.2.2*):

7.3.2.1 *Product design input*:

- the functional and performance requirements as derived from customer input, legal and regulatory requirements which apply
- useful information or experience from previous similar design efforts
- targets for product quality, life, reliability, durability, maintainability, timing and cost

7.3.2.2 *Manufacturing process design input* which may include:

- product design output data,
- targets for productivity, process capability and cost,
- customer requirements (if any), and
- experience from previous process designs.

Note: Manufacturing process design includes the use of error-proofing methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.

7.3.2.3 *Special characteristic* (including product characteristics and process parameters) for inclusion in the control plan (*Section 7.1*) to ensure compliance with customer-specific definitions/symbols, and/or to define related guidelines in their absence.

7.3.3 Design outputs. The Design (or APQP) Team Leader (?) ensures that design outputs comply with the design input requirements; include information needed for production and service provision; include or reference acceptance criteria; indicate design characteristics critical to the safe and proper operation of the product; and are approved before issuance:

7.3.3.1 *Product design outputs* expressed in terms that can be verified and validated against product design input requirements, including: design FMEAs and reliability results; product special characteristics and specifications; product error-proofing, product definition including drawings or mathematically based data; product design review results; and diagnostic guidelines:

7.3.3.2 *Manufacturing process design outputs* expressed in terms that can be verified against manufacturing process design input requirements and validated (*Section 7.5.2*), including: specifications and drawings; manufacturing process flow chart/layout; manufacturing process FMEAs; control plans; work instructions; process approval acceptance criteria; tool designs; data for quality, reliability, maintainability and measurability; results of error-proofing activities; and methods of rapid detection and feedback of product/manufacturing process nonconformities.

7.3.4 Design review

During the evolution of each design project, the Design (or APQP) Team Leader (?) conducts design reviews as planned and records results and any necessary actions. All functions concerned with the stage being reviewed are represented at the planned review(s). Design reviews are intended to assure that requirements are being fulfilled; when they are not, the Design (or APQP) Team Leader (?) utilizes input from those involved in the review to propose a remedy for each identified problem.

7.3.4.1 *Monitoring*. The Design (or APQP) Team Leader (?) monitors the design project by defining, analyzing and recording measurements at specified stages of design and reports summary results as an input to management review (*Section 5.6*). Measurements may include quality risks, costs, lead-times, and critical paths.

7.3.5 Design verification

The Design (or APQP) Team Leader (?) ensures design verification activities are carried out as planned (per the Design Plan) and records results and any necessary actions. Design verification activities are intended to determine if design output meets design input requirements; design reviews can be a form of design verification.

7.3.6 Design validation

The Design (or APQP) Team Leader (?) ensures design validation is carried out as planned (per the Design Plan) and records results and any necessary actions. Design validation is performed to ensure the product or service resulting from design efforts performs as intended for all specified or known uses/applications. As applicable, the Design (or APQP) Team Leader (?) plans and carries out or oversees:

7.3.6.1 *Design validation* to ensure it is performed in accordance with customer requirements, including program timing.

7.3.6.2 *Prototype program* to ensure: 1) it is carried out using the same suppliers, tooling and manufacturing processes as will be used in production; 2) all performance-testing activities are monitored for timely completion and conformity to requirements; and 3) technical leadership is provided to ensure outsourced services are performing as intended.

7.3.6.3 *Product approval process*, detailed in *OP 7.1* and depicted in *DFC 7.1-1*, per *PPAP-4*, through the APQP Team Leader (?), to ensure all customer engineering design record and specification requirements are properly understood and that the process has the potential to produce product consistently meeting these requirements during an actual production run at the quoted production rate. Note: In the absence of any specific instructions, we will default to a level 3 PPAP submission (*Section 7.1.1*).

7.3.7 Control of design changes

The Design (or APQP) Team Leader (?) ensures all design changes are identified, documented, reviewed, approved, communicated to all affected organizations and functions, and results and any necessary actions are recorded throughout the product program. Design change control includes an assessment of the impact of changes upon component parts and completed products, including those that may have already been delivered. Control also includes the determination of treatment required for each change, which may include verification or validation.

7.4 Purchasing

We work in partnership with our suppliers to ensure that purchased products and services meet all applicable requirements. The processes applicable to the planning, acquisition and verification of all products and services that affect customer requirements (such as subassembly, sequencing, sorting, rework and calibration services) are defined in *OP 7.4.1*, *OP 7.4.2* and *OP 8.2.4* in accordance with the policies outlined in this section.

7.4.1 Purchasing process

The type and extent of control applied to our suppliers and purchased product is dependent upon the effect on subsequent realization processes and their output, as well as consideration of other characteristics including: the type of product; the potential impact of the product on our processes, products, or services; the results of supplier evaluations; and past performance.

Purchased products are verified (*Section 7.4.3* and *Section 8.2.4*) to ensure conformity to specified purchase requirements (*Section 7.4.2*).

7.4.1.1 *Regulatory conformity*. Purchased products or materials are also verified to ensure conformity to applicable regulatory requirements.

The MAT (?) defines and documents the supplier approval process, including criteria for selection, the extent of control to be exercised, and periodic evaluation; *OP 7.4.1*. Suppliers are evaluated and selected based on their ability to supply products or services in accordance with our requirements.

7.4.1.2 *Supplier quality management system development*. Essentially, the same requirements imposed on IsoQual, Inc. are cascaded down to *our* supply base. In order to ensure the quality of the parts shipped by IsoQual, Inc, we have established systems to manage the parts and materials received from our supply base and initiate supplier development based on importance of the supplied product and supplier quality performance in accordance with supplier expectations and monitoring procedures defined in *OP 7.4.1*.

7.4.1.3 *Customer-approved sources*. Where specified (by contract, customer engineering drawing, or specification) we purchase products, materials or services from customer-approved sources.

A master list of approved suppliers is maintained to ensure we only purchase product from IsoQual qualified sources or customer-approved sources. The results of evaluations and follow/up actions are recorded.

Supplier performance is monitored by the MAT (?) per *OP 7.4.1* through one or more of the following indicators: delivered product quality; customer disruptions including field returns; delivery schedule performance (including incidents of premium freight); and special status customer notifications related to quality or delivery issues.

7.4.2 Purchasing information

The MAT (?) ensures the adequacy of specified purchase requirements prior to communication to the supplier per procedures defined in *OP 7.4.2* and the following policies:

Purchasing information communicated to our suppliers contains the appropriate data needed to clearly and fully describe requirements for purchased materials and services; including, where appropriate, requirements for approval/qualification of product, procedures, processes/systems, equipment; qualification of personnel; and quality management system requirements.

7.4.3 Verification of purchased product

The QM (?) ensures that purchased product is verified prior to use or release in accordance with provision of this section.

7.4.3.1 *Incoming Product Quality*. The QM (?) has overall responsibility for ensuring the quality of purchased products using one or more of the following methods: receipt and evaluation of statistical data; receiving inspection and/or testing (such as sampling based on performance); second or third party audits of supplier sites (when coupled with records of acceptable delivered product quality); part evaluation by a designated laboratory; and/or another method agreed with the customer. Receiving inspection is performed per *Section 8.2.4*.

The QM (?) plans and implements appropriate sampling plans and/or other statistical techniques to verify purchased product per *Section 8.1*.

All requirements for approval of purchased product and/or supplier procedures, processes, equipment, personnel, and/or quality systems are reviewed for adequacy prior to communication to the supplier per *Section 7.4.2*.

As applicable, the QM (?) documents and communicates the intended verification arrangements and method of product release related to verification activities performed at our suppliers' premises.

As needed, the MAT (?) with input and assistance from the QM and other IsoQual management and technical personnel initiates, monitors and follows on supplier corrective action requests in accordance with *OP 7.4.2*.

7.5 Production and service provision

7.5.1 Control of production and service provision

We utilize a process-focused approach to plan and control operations and support services related to production and service provision. Our initial focus is to assure the quality of process inputs - that is, employees, material, facilities and equipment, and methods. Employees must be equipped to perform the process properly through appropriate education, training, and certification. Material must meet specified requirements and be properly identified, stored, and issued. Equipment and facilities must be adequate, accurate, available and properly utilized. Work instructions and other important data must be current and correct. Methods must be appropriate and proven capable of accomplishing the desired results. The appropriateness of all these fundamental process inputs must be assured, and processes must be measured, monitored and controlled to assure effectiveness and/or to identify opportunities for improvement.

7.5.1.1 *Control plan.* The QM (?), per *Section 7.1.1*:

- Develops control plans at the system, subsystem, component, and/or material level for the product supplied, including processes producing bulk materials, as well as parts
- Develops a control plan for pre-launch and production that takes into account the design FMEA and manufacturing process FMEA outputs (*Section 7.3.3.2*).
- Ensures that production across all shifts is staffed with personnel in charge of, or delegated responsibility for product quality.

The QM (?) further ensures that control plans:

- List the controls used for manufacturing process control
- Include methods for monitoring of control exercised over special characteristics (*Section 7.3.2.3*) defined by both IsoQual and the customer
- Include customer-required information, if any
- Initiate the specified reaction plan (*Section 8.2.3.1)* when the process becomes unstable or not statistically capable
- Are reviewed and updated when any change occurs affecting product, manufacturing process, measurement logistics, supply sources or FMEA (*Section 7.1.4*)
- Are approved by the customer after IsoQual review/update (as required)

7.5.1.2 *Work instructions*. The PRO (?) prepares appropriate work instructions for all employees having responsibility for processes that impact product quality and/or employee safety (*Section 6.4.1*). The instructions are derived from sources such as the control plan and the product realization process and are accessible to the work areas where they are needed.

7.5.1.3 *Verification of job set-ups.* Job set ups are verified prior to commencing each new production run and/or when process changes are made; *Section 8.2.4*. Work instructions governing set ups and related verifications are developed and available, and use statistical methods of verification where applicable.

7.5.1.4 *Preventive and predictive maintenance*. Per *Section 6.3.1*, the MM (?) identifies key process equipment, provides resources for their maintenance, and develops an effective total preventive maintenance system (using predictive maintenance methods) that, at a minimum, includes:

- Planned maintenance activities
- Packaging and preservation of equipment, tooling, and gauging,
- Availability of replacement parts for key manufacturing equipment
- Documenting, evaluating, and improving maintenance objectives.

7.5.1.5 *Management of production tooling*. As part of manufacturing process design (*Section 7.3.3.2*, the ENG (?) provides resources and oversees efforts related to tool and gauge design, fabrication, and verification activities. The PRO (?) establishes and implements a system for production tooling management (or monitors these activities if any work is outsourced), including:

- maintenance and repair facilities and personnel
- storage and recovery
- setup
- tool changing programs for perishable tools
- tool design modification documentation, including engineering change level
- tool identification, defining the status, such as production, repair, or disposal.

7.5.1.6 *Production scheduling*. The PRO (?) schedules production to meet customer requirements and our goal to achieve 100% on-time delivery performance through IsoQual's just in-time production control system that is order driven and provides production information at key stages of product realization.

7.5.1.7 *Feedback on information from services*. Per *Section 8.2.1*, SLS and customer contact personnel (?) collect and communicate servicing concerns to Engineering, Manufacturing and other appropriate personnel for the purpose of initiating appropriate corrective, preventive or other improvement action; *Section 8.5*.

7.5.1.8 *Service Agreements with customer*. If there is a service agreement with the customer, the QM (?) will establish and implement a plan to verify the effectiveness of any:

- service centers
- special-purpose tools or measurement equipment
- training of service personnel

The PRO (?) ensures that production/service jobs are planned, scheduled, and carried out in accordance with procedures detailed in *OP 7.5.1* as summarized below:

7.5.1.a Information. Information inputs to the process include both product characteristics and appropriate work instructions containing specific work methods and/or other pertinent information, including process monitoring and verification instructions and criteria developed during product quality planning (*Section 7.1)* and/or manufacturing process development (*Section 7.3.2.2*). The PRO, through Product Line Team Leaders, Production Shift Supervisors and Production Control Supervisors, (?) ensures that all appropriate information including final product specifications, raw material characteristics and the required product parameters, is provided to production personnel throughout the product/service provision process. Such information is provided through job schedules/plans, production team meetings, work instructions posted in areas where they are needed, and/or through job specific information included in individual job packs (including control plans, where applicable).

7.5.1.b Work Instructions. The necessity for and required detail of work instructions is dependent upon the knowledge, skills, and abilities of our employees and the complexity of the work process they are assigned to perform. Product Line Team Leaders (?), with input from Engineering, Quality and other technical personnel identify critical production/service work steps in process sheets included in the job pack or other information included in work instructions posted in areas where they are needed.

7.5.1.c Equipment. The MM (?) ensures the suitability and availability of all equipment, facilities and tooling used for production and service operations; *Section 6.3*.

7.5.1.d Monitoring and Measurement Devices. The QM (?) ensures that monitoring and measurement devices capable of meeting our measurement requirements are available for use during production and service provision; *Section 7.6*.

7.5.1.e Monitoring Activities. The PRO, through Production Shift Supervisors, (?) ensures that production personnel monitor the quality of their own work and understand the procedures for reporting related problems and/or suspected nonconforming conditions; *OP 7.5.1* and *Section 8.2.3.1*. The QM (?) is responsible for planning and implementing in-process inspections needed to ensure process control and product quality; *Section 8.2.4*.

7.5.1.f *Release, Delivery, and Post-Delivery Processes.* Release of product is dependent on its compliance with all technical specifications and its ability to meet additional customer requirements including packaging, shipping, and delivery, as identified in the contract or order. The COO, through the MAT, the PRO, and the QM, (?) ensures that records of product approval are maintained and clearly indicate the authorizing employee; *Section 7.5.3.1*.

The COO (?) periodically reviews operational data as well as progress towards achievement of corporate level product/service performance objectives (*Section 5.4.1.1*) and provides related recommendations for review by MGT; *Section 5.6.1*.

7.5.2. Validation of processes for production and service provision

We define processes in which results cannot be verified by subsequent monitoring or measurement as "Special Processes"; this includes any processes where deficiencies may become apparent only after the product is in use or the service has been delivered. The ENG (?) has overall responsibility for ensuring 'Special Processes" are validated in accordance with procedures detailed in *OP 7.5.2* . As applicable, arrangements are established for: defining criteria for review and approval of the processes; approval of equipment and qualification of personnel; use of specific methods and procedures; requirements for records; and revalidation.

7.5.2.1 *Validation of process for production and service provision – Supplemental*. Process validation applies to all processes for production and service provision (*Section 7.5.1*) related to our automotive products. The APQP Team Leader (?) utilizes our a production part approval process acceptable to our customer to validate that product realization processes are capable of achieving desired results in accordance with the APQP/PPAP process detailed in *OP 7.1* and depicted in *DFC 7.1-1*.

7.5.3 Identification and traceability

The ENG (?) has overall responsibility for establishing and maintaining product identification throughout all stages of design, production, installation and delivery in accordance with procedures defined in *OP 7.5.3*. Where product traceability is a customer-specified requirement, appropriate controls and records are established and maintained.

7.5.3.1 *Identification and traceability – Supplemental*. The identification and status of product is established and maintained throughout all product and service provision processes.

We establish and maintain product monitoring and measurement status through the use of both physical identification tags/labels and electronic records (identify your electronic record system here, if applicable). Additionally, physical location in clearly designated hold area is an indicator of product status; however, physical location in production process areas may serve as an indicator of product status only where product identification and inspection status is inherently obvious, e.g. in our automated production transfer process (name your process(es) here where location will provide inspection and test status, if/as applicable). The COO, through the MAT, the PRO, the MM, and the QM (?), ensures that all incoming, in-process, and final product is suitably identified and the current status is appropriately tracked and displayed in accordance with procedures detailed in *OP 7.5.3*.

Where contractually required, the QM (?) plans for, establishes and maintains appropriate traceability records in accordance with customer requirements; *Section 7.1*. At a minimum, where products are made in lots or batches we identify and record a unique lot or batch number and related information on the job traveler; *Section 7.5.1* and *OP 7.5.3*.

7.5.4 Customer property

Customer property includes customer-owned material, tools (including returnable packaging), tooling (including test/inspection tooling and equipment), and intellectual property. We identify, verify, protect and maintain customer property provided for use or incorporation into the product, by applying the same process controls as we do to purchased product (*Section 7.4*).

Whenever customer-specified requirements for property management are beyond the control or capability of our established QMS, the QM (?) has overall responsibility for planning, documenting and communicating such requirements to all appropriate personnel as a part of product quality planning; *Section 7.1*.

7.5.4.1 *Customer-owned production tooling*. All customer-owned production tooling is permanently marked so the ownership of each item is visible and can be determined. Additional special requirements applicable to customer supplied product are detailed in *OP 7.5.4*. The QM (?) ensures that lost, damaged or unsuitable customer property is recorded and immediately reported to the customer; *Section 8.3.3*.

7.5.5 Preservation of product

The MAT (?) has overall responsibility for establishing and implementing a material management system to ensure product conformity is preserved during internal processing and delivery to the intended destination. This system, defined in *OP 7.5.5*, includes the handling, storage, packaging, delivery, and protection of final product as well as raw materials and in-process constituents of the final product, to support our goal of 100% on-time delivery performance and ensure:

- Components and products are handled and stored in a manner that prevents damage or deterioration pending use or delivery.
- Each department ensures controls are implemented to prevent mixing conforming and non-conforming materials.
- Packing ensures specified or original manufacturing packaging is utilized.
- All components and products are suitably packed to prevent deterioration or damage during storage and delivery.

7.5.5.1 *Storage and inventory*. In order to detect deterioration, the condition of stock is periodically assessed. IsoQual uses an automated inventory management system to optimize inventory turns over time and assure stock rotation on a 'first-in-first-out' (FIFO) basis. Further, obsolete product (including expired age dated material, e.g.) is controlled as nonconforming product; *Section 8.3.1*.

7.5.5.2 *Advanced Shipping Notification (ASN)*. IsoQual, Inc. utilizes an ASN to facilitate the electronic transfer of data (see *OP 7.5.5*) utilized by our customers to:

- determine and confirm goods in transit.
- verify and receive products into their system.
- create an electronic invoice that will generate payment.

7.6 Control of monitoring and measuring devices

The QM (?), is responsible for establishing and maintaining an effective system for identifying, selecting and controlling the use of monitoring and measuring devices used to provide evidence of product conformance to established requirements. These controls, defined in *OP 7.6*, apply to IsoQual owned, customer-owned and employee-owned devices.

We determine the measurements to be made and the accuracy required to assure conformity of our product to specified requirements. We identify and select monitoring and measuring devices and verify their capability of meeting such requirements prior to use. In addition, the ENG (?) documents the method for confirming the ability of software to satisfy the intended application; *Section 7.3.3.2*.

Monitoring and measuring devices are used and controlled in a manner that ensures continuing suitability; this includes ensuring that the environmental conditions are suitable for the calibration, inspections, measurements and tests being carried out. We also define the processes employed for the on-going calibration, control and maintenance of monitoring and measuring devices including their identification, location, frequency/method of checks, uses/acceptance criteria and the action to be taken when results are unsatisfactory.

7.6.a All monitoring and measuring devices that can affect product quality are identified and calibrated at prescribed intervals against certified equipment having a known valid relationship to internationally or nationally known standards. Where no such standards exist, the basis used for calibration is documented. IsoQual, Inc. does not have an internal laboratory facility and therefore cannot perform all required inspections, tests and/or calibrations; accordingly, external laboratories used for inspection, test or calibration services are selected, qualified and monitored per *Section 7.4*.

7.6.b When monitoring and measuring devices are found to be out of calibration (or when calibration status is not known), they are adjusted or re-adjusted as necessary and the validity of previous measuring results is documented; actions taken are documented, including appropriate corrective actions to remedy the situation and preclude its recurrence; *Section 8.5.2*.

7.6.c Appropriate calibration records are maintained to document results of calibration activities

(*Section 4.2.4*) and suitable indicators are used to show current calibration status. A number or other identifier is used to provide traceability to the device calibration record; *Section 7.6.2*.

7.6.d All monitoring and measuring devices are safeguarded from adjustment that would invalidate the calibration.

7.6.e All monitoring and measuring devices are handled, maintained and stored in a manner that ensures accuracy and fitness for use is maintained.

7.6.1 *Measurement systems analysis*. Statistical studies are conducted to analyze the variation present in the results of each type of measuring and test equipment system (referenced in the applicable control plan). Such measurement systems analyses conform to applicable customer reference manuals including the AIAG "Measurement System Analysis" reference manual (identify your customer specific requirements or guidance document here); other analytical methods and acceptance criteria are only used if approved by the customer; see *OP 7.6*.

7.6.2 *Calibration/verification records*. Records of the calibration/verification activity for all gauges, measuring, and test equipment needed to provide evidence of product conformity to determined requirements, including employee and customer owned equipment, includes:

- Equipment identification, including the measurement standard against which the equipment is calibrated
- Revisions following engineering changes
- Any out-of-specification readings as received for calibration/verification
- An assessment of the impact of an out-of-specification condition
- Statements of conformance to specification after calibration/verification
- Notification to the customer if suspect product or material has been shipped

7.6.3 *Laboratory Requirements*.

7.6.3.1 *Internal Laboratory*. The QM (?) manages our internal laboratory and maintains records that define/demonstrate its capability to perform the required inspection, test or calibration services; see *OP 7.6*.

7.6.3.2 *External Laboratory*. The QM (?) ensures external laboratories used for inspection, test, or calibration services are either acceptable to the customer or accredited to *ISO 17025* (or the national equivalent); see *OP 7.6* for calibration laboratories and *OP 8.2.4* for inspection and test laboratories.

8. Measurement, Analysis and Improvement

8.1 General

This section describes how we define, plan, and implement the monitoring, measurement, analysis and improvement activities needed to assure product and QMS conformity and achieve continual QMS improvement. These activities include assessment of customer satisfaction, conduct of internal audits, process monitoring and measurement, and product monitoring and measurement. *OP 8.1* details procedures governing the selection and use of appropriate statistical techniques used in monitoring, measurement, analysis and improvement activities.

8.1.1 *Identification of Statistical Tools*. The QM (?) ensures that statistical tools used to monitor QMS processes are identified during quality planning and included control plans, as applicable; *Section 7.1*. Statistical techniques for on-going process control and improvement are established per (*OP 8.1*) and the AIAG "Statistical Process Control" (SPC) reference manual, *SPC-3*, (state your reference here) and associated customer specific requirements documents.

8.1.2 *Knowledge of Basic Statistical Concepts*. Employees utilizing statistical tools to manage, verify or perform work will attend a Basic Statistics course containing an overview on basic concepts such as variation, control (stability) process capability; over-adjustments will be understood and utilized throughout the organization; see *Section 6.2.2*.

8.2 Monitoring and measurement

8.2.1 Customer Satisfaction

Customers are the reason we exist and drive our quality policy "to meet or exceed customer requirements." SLS (?) has overall responsibility for identifying and reviewing customer requirements (see *Section 7.2.1* and *Section 7.2.2*) and for monitoring and measuring customer satisfaction per procedures contained in *OP 8.2.1*, summarized as follows:

Data collected by customer contact personnel during routine communications (*Section 7.2.3*) provide our primary basis for assessing customer satisfaction. Sales personnel and Customer Service staff (?) utilize a very simple customer satisfaction survey form (hard copy or electronic) to ascertain the customer's overall perception of how well we are meeting their requirements and to document any recommendations for improvement.

8.2.1.1 *Customer Satisfaction – Supplemental*. At a minimum, related performance indicators include, but are not limited to:

- delivered part quality performance
- customer disruptions / field returns
- delivery schedule performance / incidents of premium freight
- customer notifications related to quality and delivery issues.

Further, product realization processes are monitored (*Section 8.2.3.1*) to demonstrate compliance with customer requirements (for product quality and/or efficiency, as applicable).

Customer complaints (whether received in writing, verbally or electronically through our web site customer contact form) are immediately forwarded to appropriate Sales or Customer Service personnel (?) for action. If these personnel cannot resolve the issue to the customer's satisfaction, then the complaint is transferred to SLS (?) for assignment to another appropriate manager or function for resolution. Customer complaints are documented and monitored through resolution through our management action system; *Section 8.5*.

Customer survey data along with other customer feedback (including written or verbal complaints and information collected from our web site's customer feedback form) is reviewed daily by Sales personnel and Customer Service staff (?) to initiate any improvement or corrective/preventive actions needed; *Section 8.5*.

SLS (?) periodically reviews customer satisfaction survey data and other customer feedback (including complaints), as well as progress towards achievement of corporate level customer satisfaction improvement objectives (*Section 5.4.1)* and provides related recommendations for review by MGT; *Section 5.6*.

8.2.2 Internal audit

Internal audit results are critical inputs to aid in assessing the effectiveness of our QMS, in identifying opportunities for improvement, and in promoting awareness of customer requirements and effectiveness of the QMS to our workforce.

8.2.2.1 *Quality management system audit*. We conduct QMS audits to determine conformity to *ISO/TS 16949:2009* and any additional QMS requirements that may apply (*ISO 14001:2004*, for example). Our overall measure of QMS effectiveness is the absence of repeat problems/findings, as an indicator that our QMS was effective in eliminating the cause of such problems.

8.2.2.2 *Manufacturing process audit*. Audits of our key product realization processes are conducted annually to determine their effectiveness (*Section 8.2.3*) and to identify opportunities for improvement (*Section 8.5.1.2*). Layered process audits (LPA) are conducted if/as required by *customer specific requirements* (see the *LPA Overview* and our *process audit checklist*).

8.2.2.3 *Product audit*. Product audits are also conducted at appropriate stages of production and delivery to verify conformance to all specified requirements contained in the control plan (*Section 8.2.4*) using our *product audit checklist*.

Internal audits are conducted in accordance with a published schedule that identifies the audit scope and frequency. The schedule is updated on the basis of status and importance of the activity to be audited and previous audit results.

8.2.2.4 *Internal Audit Plans*. Each of our key QMS processes (*DFC 4.1*), with a special emphasis on our 'core' customer oriented processes (*COP 4.1*) and our unique product realization processes (Section 8.2.3.1), is reviewed at least once annually to determine effectiveness.

The QMS process, function or quality system element under review is effective if it is achieving the desired results or established objectives; *Section 5.4.1.* In addition, employee involvement in identifying process effectiveness or efficiency improvements is actively sought during internal audits. Internal audit results are used to determine the scope, nature and frequency of future internal audits of processes, products, functions or quality system elements where ineffectiveness or inefficiency is most likely to be found. Responsible managers may also request that the audit be used to gather "value added" data serving as input to aid in monitoring, measurement and improvement of QMS processes and systems; *Section 8.2.3* and *Section 8.5.1*.

ISO (?) has overall responsibility for managing the internal audit process in accordance with *OP 8.2.2* as summarized below:

8.2.2.5 *Auditor qualification*. Internal auditors are qualified to audit to *ISO/TS 16949:2009* requirements (*Section 6.2.2*). Audits are carried out by qualified personnel who do not have direct responsibility for the activity being audited. Audit checklists are prepared and used to aid in ensuring audit consistency and comprehensiveness (see *Internal Auditor Training* materials).

Auditors record audit results and submit findings to management personnel with responsibility for the process, function or quality system element audited.

Management responsible for the area audited implement timely corrective action to eliminate detected non-conformances and their causes, and initiate other appropriate action in response to opportunities for improvement identified by process participants or managers. Follow-ups are conducted to verify timely and effective implementation of the proposed action.

ISO (?) maintains all internal audit records, including internal auditor training records, results of internal audits and related follow-ups; periodically reviews internal audit results as well as progress towards achievement of corporate level objectives aimed at improving overall QMS effectiveness (*Section 5.4.1*); and provides related recommendations for review by MGT; *Section 5.6*.

8.2.3 Monitoring and measurement of processes

We apply suitable methods for monitoring and measuring all QMS processes. QMS processes depicted in *DFC 4.1* are documented measured, controlled and evaluated (*Section 8.2.2.1*) to ensure they are effective and efficient (i.e. achieve desired results) and to identify opportunities for improvement. At a minimum, managers with overall responsibility for carrying out a QMS process, analyzes process performance (*Section 8.4*) and takes appropriate improvement, corrective or preventive action (*Section 8.5*); also see *process management overview*.

We conduct process audits (*Section 8.2.2.2*) to verify QMS process conformance and identify opportunities for improvement; manufacturing process audits are conducted annually.

In addition we monitor and measure manufacturing processes to ensure to ensure continuing process capability and suitable performance as specified by the customer part approval process (PPAP) requirements (*Section 7.3.6.3*).

8.2.3.1 *Monitoring and measurement of manufacturing processes.*

Process Capability. As part of manufacturing process design (*Section 7.3.3.2*), the ENG (?), through our APQP/PPAP process (*Section 7.1.1*), ensures process studies are performed on all new product realization processes to verify process capability and provide additional input for process control. Process capability study results, where applicable, and specifications (including methods of production, measurement and test, and maintenance instructions) are documented. Acceptance criteria (as well as objectives for process capability, reliability, maintainability and availability) and appropriate reaction plans are included in control plans (see *Section 7.5.1.1*) and/or job packs (*Section 7.5.1*). For attribute data sampling, the acceptance level shall be ZERO DEFECTS.

Job Set Up. Job set ups (*Section 7.5.1.4*) are verified (*Section 8.2.4*) prior to commencing each new production run and when process changes are made.

Process Monitoring. Processes are monitored by process operators per applicable instructions (*Section 7.5.1.2*) and procedures defined in *OP 8.2.3*. Significant process events, such as tool change or machine repair are recorded. Control plans and process flow diagrams are implemented (*Section 7.5.1.1*) to ensure adherence to the specified measurement techniques, sampling plans, acceptance criteria, and reaction plans when acceptance criteria is not met; see *Section 7.1.1* and *Section 8.1*. Production personnel follow documented reaction plans when processes become unstable or no longer capable. The QM (?) then initiates a corrective action plan indicating the specific timing and assigned responsibilities to assure the process becomes stable and capable. As required, the corrective action plan is review with and approved by the customer and usually requires application of a customer recognized or approved problem solving approach (*Section 8.5.2.1*).

8.2.4 Monitoring and measurement of product

The QM (?) has overall responsibility for planning (*Section 7.1*) and implementing inspection and test activities needed to verify product requirements are met at appropriate stages of the product realization process in accordance with the applicable control plan. When selecting product parameters to monitor compliance to internal and external requirements, product characteristics are determined leading to the types of measurement, suitable measurement means, and the required capability and inspection/test skills needed.

The scope of our product monitoring and measurement system (defined in *OP 8.2.4*) includes receiving inspection, job set up verification, in-process inspection, final inspection and test, layout inspection and functional test, and special consideration regarding monitoring and measurement of appearance items.

Receiving Inspection. Incoming product is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements in accordance with the control plan and/or documented procedures. Methods used to verify incoming product (see *Section 7.4.3*) may include: receipt and evaluation of statistical data by the supplier; formal receiving inspection and/or test (see *OP 8.2.4*), evaluation by accredited laboratories; or source

inspections.

Job Set Up Verification. Job set ups are verified per procedures defined in *OP 8.2.4* prior to commencing each new production run and/or when process changes are made.

In-process Inspection. Formal in-process inspections are performed by Quality Control (QC) personnel (?) in accordance with the control plan and *OP 8.2.4*. Manufacturing process monitoring (*Section 8.2.3.1*) is performed by production personnel in accordance with the applicable control plan (*Section 7.5.1.1*).

Final Inspection and Test. All finished products and completed services are verified by final inspections/tests specified in the control plan and *OP 8.2.4*.

Release. Products are not released for further processing or delivery until we have objective evidence that all requirements have been met.

Evidence of Conformity. Test and inspection records are maintained for a minimum of three years. These records include final inspection authority and identify and confirm that all critical parameters are in accordance with established requirements and specifications. Additionally, product samples are stored for a minimum of 3 years.

Product Release and Delivery. Product is not normally released or delivered until all planned inspections and tests have been completed, and records have been maintained providing evidence of conformity with acceptance criteria and identifying the person(s) authorizing release. In rare cases (due to customer demands and/or production emergencies) unverified product may be released or delivered under controlled conditions of positive recall documented and authorized by the QM (?) and, where applicable, approved by the customer. Nonconforming (or suspect) product is identified and controlled to prevent its inadvertent use; *Section 8.3*.

8.2.4.1 *Layout inspection and functional testing*. As required, an annual layout inspection and functional verification to applicable customer engineering material and performance standards is performed for each product specified in the control plan by QC personnel (?) in accordance with *OP 8.2.4*. Results are retained and available for customer review.

8.2.4.2 *Appearance Items*. For parts designated by the customer as “appearance items” IsoQual provides:

- Appropriate resources, including lighting for evaluation (*Section 6.3*)
- Masters for color, grain, gloss, metallic brilliance, texture, distinctness of image, as appropriate
- Maintenance and control of appearance masters and evaluation equipment
- Verification that personnel making appearance evaluations are competent and qualified to do so (*Section 6.2.2*)

8.3 Control of nonconforming product

The QM (?) has overall responsibility for implementing an effective process for identifying, documenting, segregating, evaluating, and disposing of nonconforming product. Personnel responsible for product quality have the authority to stop production to correct quality problems in accordance with *OP 8.3*; related procedures are summarized below:

Identification. Identification of nonconforming product originates from inspection, internal testing, product audits or customer complaints. Employees clearly mark or otherwise identify nonconforming product or suspect material.

Documentation. The QM (?) or authorized QC personnel (?) enter the nonconformance into the corrective action system (*Section 8.5.2*) identifying the nonconforming product and lot number if applicable, description of nonconformance, and location where the nonconforming product is being held pending further review or disposition.

Segregation. Nonconforming product is segregated pending evaluation and disposition.

Evaluation. The QM through authorized QC personnel (?), perform the initial evaluation of nonconforming product in accordance with approved test and inspection procedures. Where needed, Engineering, Production and other technical personnel may become involved in the evaluation and recommendation for disposition.

Disposition. The results of the evaluation and resultant disposition determinations are documented. Dispositions resulting from the evaluation of nonconforming product may include: rework to meet specified requirements; re-grade for an alternative application; use as is (under customer concession or other required approval authority); obtain (from relevant authority) a waiver of or deviation from requirements; return to supplier; scrap or other disposal.

8.3.a. Correction and Re-verification. Reworked nonconforming product is re-verified after correction to demonstrate conformity to original requirements.

8.3.b Product Recall. In the event nonconforming product is detected after delivery or use has started, the QM (?) notifies the customer and initiates action appropriate to the effects, or potential effects, of the nonconformity. Where appropriate, product recall is initiated based on trace and recall data and records; *Section 7.5.3*.

8.3.c Nonconformance Reporting. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, is maintained in accordance with *OP 8.3*, applicable inspection and test procedures, and *Section 4.2.4*.

8.3.1 *Control of nonconforming product – Supplemental*. Product with unidentified (*Section 7.5.3*) or suspect status is classified and processed as nonconforming.

8.3.2 *Instructions for Reworked Product*. Instructions for rework, including re-inspection requirements, are documented by the QM (?) and made available to and utilized by appropriate production personnel.

8.3.3 *Customer Information*. Responsible Sales or Customer Service personnel (?) notify the customer immediately upon discovering that nonconforming product has been shipped.

8.3.4 *Customer Waiver*. Where the customer has previously approved the production process, the ENG (?) obtains a customer concession or deviation permit prior to further processing whenever the product or product realization process is different from that which is currently approved. The ENG (?) maintains a record of the expiration date or quantity authorized; ensures compliance with the original or superseding specifications and requirements when the authorization expires; and ensures material shipped on an authorization is properly identified in each shipping container. This waiver process also applies to purchased product and IsoQual will provide evidence of concurrence with the supplier (if applicable) before submission to the customer. A deviation request will be accompanied by an action plan identifying root cause and steps to implement a permanent corrective action. Procedures governing the processing of customer waivers and deviation are detailed in WI 8.3.

8.3.5 Nonconformance reports requested by the customer (usually if/when a customer receives material or service that fails to conform to applicable quality and delivery specifications) are processed per customer requirements and the procedures defined in *OP 8.3*.

8.3.6 If placed on "containment status" (due to continued poor performance and/or failure to achieve goals and objectives), IsoQual, Inc. will take all actions required by the customer, and guidelines contained in *OP 8.3*.

8.4 Analysis of data

MGT and other officers, managers and supervisors collect and analyze data using appropriate statistical techniques (*Section 8.1*) to determine the suitability and effectiveness of key QMS processes (*DFC 4.1*) applicable to their area(s) of responsibility and to identify opportunities for improvement. At a minimum, data is analyzed to assess achievement of the corporate level quality objectives (*Section 5.4.1*).

We manage our key QMS processes through the use/application of what we call *Process Assessment Worksheets (PAWs)*, *Form 8.4-1*, and associated 'Turtle Diagrams', *Form 8.4-2*, which are used to define and analyze the selected process in terms of inputs, throughputs/activities, and outputs. Related guidance and information is contained in our *Process Management Guide* and in *WI 8.4-2* and *Section 8.5.1*.

A process is effective if desired results are achieved. Effectiveness can be measured in terms of product quality, process accuracy, delivery/schedule performance, cost/budget performance, employee/function performance against established objectives, and/or customer satisfaction.

A process is efficient when resource utilization is optimal. Efficiency can be measured in terms of total resource utilization, productivity indicators, and or the cost of poor quality (such as waste/rework costs or hours).

8.4.1 *Analysis and Use of Data*. Trends in quality and operational performance are compared with progress toward objectives and related recommendations for improvement are developed and are presented to MGT for review and action during management reviews; *Section 5.6*.

8.5 Improvement

8.5.1 Continual improvement

8.5.1.1 *Continual improvement of the organization*. At IsoQual, the continual improvement process begins with the establishment of our quality policy (*Section 5.3*) and objectives for improvement (*Section 5.4.1*), based on objectives contained in our Business Plan and customer targets/goals. Customer satisfaction, internal audit, process and product performance data, and the cost of poor quality are then compared to progress against objectives to identify additional opportunities for improvement; *Section 8.4*. Appropriate improvement initiates are established, supported and monitored for achievement through the use of a Continual Improvement Form (CIF), *Form 8.5-6*, and our management review process (*Section 5.6*). We also consider corrective and preventive actions a vital part of our continual improvement program. Corrective actions are initiated when desired results are not achieved and preventive actions are initiated to prevent the occurrence of problems or to implement other improvement actions. Management Action Requests (MARs), *Form 8.5-1*, are used to document improvement, corrective and preventive actions; all management actions are prioritized and implemented on the basis of data analysis (*Section 8.4*): the impact of failures/problems is used to prioritize needed corrective actions; risks are evaluated to identify and prioritize needed preventive actions; and cost/benefit analyses are performed to identify and prioritize needed management actions. Procedures governing our management action system are detailed in *OP 8.5*.

The overall effectiveness of management action system (including corrective and preventive actions taken as well as the overall progress towards achieving corporate level improvement objectives) is assessed through our management review process (*Section 5.6*).

Essentially, such actions are effective if the problems corrected do not reoccur, potential problems identified do not occur, and other improvement actions accomplish the desired results or objectives. Inputs to the management review process are used to establish new/changed improvement objectives and to initiate/prioritize additional improvement actions; *Section 5.6*.

8.5.1.2 *Manufacturing process improvement*. The ENG (?) plans and implements continual improvement of manufacturing processes that are capable and stable, or where product characteristics are predictable and meet customer requirements. We identify such opportunities through analysis of results of manufacturing process monitoring activities (*Section 8.2.3.1*), product monitoring and measurement activities (*Section 8.2.4*), and process oriented audits (*Section 8.2.2*) of key manufacturing processes at least once annually. The overall objective of manufacturing process improvement is to reduce part-to-part variation and eliminate all waste. As warranted, improved controls and/or to methods to reduce variation in product characteristics and manufacturing process parameters are instituted using the same methodology as prescribed for manufacturing process design (*Section 7.3.3.2*) and validation (*Section 7.3.6.3*). The ENG (?) summarizes and reports results of manufacturing process improvement activities to MGT for review (*Section 5.6*).

ISO (?) has overall responsibility for establishing and implementing an effective management action system (*OP 8.5*) which includes improvement actions, as outlined in *Section 8.5.1* above, and corrective and preventive actions as outlined in *Section 8.5.2* and *Section 8.5.3* following.:

8.5.2 Corrective action

Evidence of nonconforming product, customer dissatisfaction, or ineffective processes is used to drive our corrective action system because a problem exists requiring immediate correction and possible additional action aimed at eliminating or reducing the likelihood of its recurrence. Management with responsibility and authority for corrective action are notified promptly of product or process non-conformities. Investigating and eliminating the root cause of these failures is a critical part of our corrective action process. Key features of our corrective action process, defined in *OP 8.5*, include:

8.5.2.1 *Problem Solving*. We utilize a structured (“8D”) problem solving approach (state your approach here) that meets customer specified requirements and leads to root cause identification and elimination.

8.5.2.2 *Error-Proofing*. We also use error-proofing methods in the corrective action process.

8.5.2.3 *Corrective Action Impact*. We apply corrective action and implemented controls to other similar processes and products to eliminate the cause of the nonconformity.

8.5.2.4 *Rejected Product Test/Analysis*. The QM (?) analyzes parts rejected by the customer and initiate corrective action to prevent recurrence; records of these analyses are retained and made available upon request by the customer. Cycle time related to rejected product analysis is consistent with the determination of root cause, corrective action, and monitoring effectiveness of implementation. Related procedures are detailed in *OP 8.3*.

Follow-ups are conducted (through the internal audit process; *Section 8.2.2)* to ensure that effective corrective action is taken appropriate to the impact of the problem encountered. In addition, ISO (?) summarizes and analyzes corrective action data to identify trends needed to assess overall effectiveness of the corrective action system and to develop related recommendations for improvement. The corrective action system is considered effective if specific problems are corrected and data indicates that the same or similar problems have not recurred. Results of this analysis and related recommendations are presented to MGT for review and action during management reviews; *Section 5.6*.

8.5.3 Preventive action

Data from internal audits, customer feedback, employee suggestions, and other appropriate data is collected and analyzed (*Section 8.4*) to identify the actions needed to eliminate the causes of potential problems and thereby prevent their occurrence. We also utilize Potential Failure Modes and Effects Analysis (FMEA) tools to identify potential failures and their causes. Investigating and eliminating the root cause of potential failures is a critical part of our preventive action process. We review and initiate preventive actions through our preventive action process defined in *OP 8.5*. We apply controls and follow-up to ensure that effective preventive action is taken appropriate to the risk and impact of potential problems and losses. In addition, ISO (?) summarizes and analyzes preventive action data to identify trends needed to assess overall effectiveness of the preventive action system and to develop related recommendations for improvement. The preventive action process is considered effective if potential losses were avoided. Results of this analysis and related recommendations are presented to MGT for review and action during management reviews; *Section 5.6*.

Appendix A

List of Key Internal QMS Documents Referenced in this Manual

(master lists for these and other QMS Documents are defined in *OP 4.2.3*)

(list all internal documents referenced in your manual)

Document No.	**Title**
QSM	*Quality System Manual*
COP 4.1	*Customer Oriented Process Model*
DFC 4.1	*Overall QMS Process Sequence and Interaction*
OP 4.2.3	*Control of Documents*
OP 4.2.4	*Control of Records*
Form 5.5.1.	*Organization Chart*
OP 5.6	*Management Review*
OP 6.2.2	*Competence, Awareness and Training*
OP 6.3	*Facilities and Equipment Maintenance*
OP 7.1	*Product Quality Planning*
DFC 7.1-1	*APQP/PPAP Process (for Automotive Products)*
OP 7.2.2	*Product Requirements Identification and Review*
OP 7.3	*Design and Development*
OP 7.4.1	*Supplier Evaluation*
OP 7.4.2	*Purchasing*
OP 7.5.1	*Production Planning and Control*
OP 7.5.2	*Validation of Product Realization Processes*
OP 7.5.3	*Production Identification and Traceability*
OP 7.5.4	*Control of Customer Supplied Property*
OP 7.5.5	*Preservation of Product*
OP 7.6	*Control of Monitoring and Measuring Devices*
OP 8.1	*Statistical Techniques*
OP 8.2.1	*Customer Satisfaction*
OP 8.2.2	*Internal Audit*
OP 8.2.3	*Monitoring and Measurement of Processes*
OP 8.2.4	*Monitoring and Measurement of Product*
OP 8.3	*Control of Nonconforming Product*
OP 8.5	*Management Action System*
Form 8.5-1	*Management Action Request (MAR)*
Form 8.5-6	*Continual Improvement Form (CIF)*

Appendix B
Terms and Definitions

Acronyms: (list all acronyms contained in your manual and other key QMS documents):

APQP	–	Advanced Product Quality Planning
CCF	–	Customer Complaint Form
CEO	–	Chief Executive Officer
CFO	–	Chief Financial Officer
CIF	–	Continual Improvement Form
COO	–	Chief Operating Officer
COP	–	Customer Oriented Process
CP	–	Control Plan
C_{pk}	–	Process Capability
CR	–	Customer Representative
CSF	–	Customer Satisfaction Form
DCN	–	Document Change Notice
DFC	–	Deployment Flowchart
DVP	–	Design Verification Plan
EIFIR	–	End Item Final Inspection Report
ENG	–	Engineering Manager
FMEA	–	Failure Mode and Effects Analysis
FSS	–	Full Service Supplier
GRR	–	Gage Repeatability and Reproducibility
HRO	–	Human Resources Officer
IM&TE	–	Inspection, Measuring and Test Equipment
ISM	–	Information Systems Manager
IR	–	Inspection Report
LPA	–	Layered Process Audit
MAR	–	Management Action Request
MEA	–	Measurement Error Analysis
MGT	–	Top Management
MAT	–	Materials Manager
MM	–	Maintenance Manager
MSA	–	Measurement Systems Analysis
NC	–	Nonconforming
OEM	–	Original Equipment Manufacturer
OI	–	Opportunity for Improvement
OJT	–	On-the-Job Training
OP	–	Operating Procedure
PAW	–	Process (or System) Assessment Worksheet
PCS	–	Process Capability Study
PFD	–	Process Flow Diagram
PM	–	Preventive Maintenance
PRO	–	Production Manager
PPAP	–	Production Part Approval Process
PSW	–	Part Submission Warrant

QM	–	Quality Manager
QMS	–	Quality Management System
QSA	–	Quality System Assessment
QSM	–	Quality System Manual
SCAR	–	Supplier Corrective Action Request
SLS	–	Sales Manager
SM	–	Safety Manager
SPC	–	Statistical Process Control
TM	–	Training Manager
WI	–	Work Instruction

Terms and Definitions. Terms and definitions contained *ISO 9000:2005* as supplemented by terms defined in *ISO/TS 16949:2009*, *Section 3.1*; contact ISO to obtain or view copies of these documents. Terms and definitions contained in this manual and unique to our organization or business are listed below; when there is a difference between the definition of terms, the definitions given in *ISO 9000:2005* and *ISO/TS 16949:2009*, *Section 3.1* apply. Customer definitions will take precedence over all other definitions.

(list all unique terms and definitions contained in this manual)

Deployment Flow Charting: a technique employed at IsoQual, Inc. to visually depict responsibilities for and the sequence and interaction of one or more related processes. Resultant deployment flow charts (*DFCs*) may be used to supplement or replace verbiage that would otherwise be needed in an OP or other QMS document, but are most often used by responsible managers (or internal auditors) to determine and document key process events, interfaces, decision points, and relevant process outputs/records as a basis for process development, monitoring and/or improvement.

Process Assessment: a technique employed at IsoQual, Inc. to summarize key process inputs, outputs, control, measures of effectiveness/efficiency and other process data; resultant process assessment worksheets (*PAWs*) or 'equivalent' '*Turtle Diagrams*' are most often used by responsible managers (or internal auditors) to determine and document relevant process metrics as a basis for process development, monitoring and/or improvement. Another important and significant tool used to monitor/track objectives is the *Continual Improvement Form* (CIF).

(Note: For information on use/application of IsoQual, Inc. products,
see our Product User Guide - TS and/or *WI 4.2.3-5*)

Best wishes for success as you
"***Make the Move from Conformance to Performance***"

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