THE LEE COMPANY

INDUSTRIAL MICROHYDRAULICS GROUP

82 Pequot Park Road
Westbrook, CT 06498

QUALITY MANUAL

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0.1 Forward

INTRODUCTION

This Quality Manual describes the policies and group-wide control system of The Industrial Microhydraulics Group (the IMH Group), of The Lee Company, Quality Management System (QMS). This QMS addresses the requirements of the ISO 9001:2015 QMS Standard, IATF 16949:2016 Automotive QMS Standard, and customer specific requirements when contractually obligated. The IMH acronym will identify the organization whose QMS is detailed in this document.

THE CONTINUING STORY OF THE LEE COMPANY INNOVATION

For over 68 years, The Lee Company has pioneered the design and development of miniature fluid control components. Since its founding in 1948, The Lee Company premise has been to economically solve problems where existing hardware is either not immediately available or is too cumbersome. The Lee Company continues to set the standards for fluid control components through innovations developed at our Technical Centers in Essex and Westbrook, Connecticut.

The name of this organization is the IMH Group. It is located at 82 Pequot Park Road, Westbrook, Connecticut, 06498. The company manufactures hydraulic & pneumatic components for the industrial, medical, and automotive industries. the IMH Group was founded in 1991. Products are produced to internal design specifications and marketed as such. Customer requirements are incorporated into our design and development process.

THE LEE COMPANY VISION STATEMENT

Together, through continual innovation of products and processes we will continue to dominate the world market for mission critical miniature hydraulic components.

IMH GROUP MISSION

The mission of the IMH Group is to design and build state of the art products that exceed customers' expectations for utility, performance, and quality. the IMH Group constantly strives to improve the product designs, the manufacturing process, and the QMS. The ultimate goal is zero defects and a satisfied internal and external customer.

1.1 Scope

This manual contains general descriptions of the components of our QMS and how it applies to risk, product and process quality, customer satisfaction, and ongoing improvement. Supporting documents, referenced in sections of this manual provide more specific guidance to quality related activities. The ISO 9001:2015 and QMS Standard and IATF 16949:2016 Automotive QMS Standard provides specific guidance to the structure of our QMS; therefore, the organization of our Quality Manual is based on the organization of these Standards and Annex SL.

The Lee Company IMH Group has established and maintains a QMS which meets the requirements of the ISO 9001:2015 QMS Standard, IATF 16949:2016 Automotive QMS Standard, and customer specific requirements (when contractually obligated) for the design, development, and manufacturing of microhydraulic control components (see Section 4.3.2).

2.0 Approval & Assignment

2.1 Approval

Every effort has been made to make this manual as complete and accurate as possible. However, any suggestions for improvement are welcome and should be directed to the Quality Assurance Manager (Management Representative).

2.2 Assignment

The Quality Manual is controlled in accordance with QSP 1.1 - Document & Data Control. Unless otherwise notified, the manual is considered uncontrolled if emailed or printed. Since this manual is a controlled document, DO NOT MAKE UNAUTHORIZED COPIES. If copies are needed, contact the Management Representative.

3.0 Terms & Definitions

3.1 Terms & Definitions

The Terms and Definitions contained in this Quality Manual are described within and/or in applicable procedures, work instructions, etc. as required. Reference ISO 9000, and IATF 16949 for terms and definitions that may also apply.

4.0 Context of the Organization

4.1 Understanding the Organization and its Context

We have determined the external and internal issues that are relevant to our company's purpose and strategic direction and to the effect these issues have on our ability to achieve our intended results. We have done this initially through analyzing our strengths, weaknesses, opportunities, and threats (SWOT). As an initial output of this process we have taken into consideration external issues arising from legal, technological, competitive, market, cultural, social and economic environments as well as internal issues related to values, culture, knowledge and performance of The Lee Company IMH Group.

We monitor and review our QMS through a risk-based approach. The following processes are considered key processes of our QMS: QSP 1.6 - Customer-Related Processes, QSP 1.7 - Contract Review, QSP 1.9 - Design and Development, QSP 1.11 - Purchasing, and QSP 1.13 - Production & Service Provision. Risk assessment related to these significant processes, and others as necessary, has been completed to identify the impact/risk on our business and customers, both internally and externally. We monitor and review these processes using our Quality Objectives, Management Reviews, internal audits, day to day activities, and other processes. In addition, our QSP 1.24 - Risk Management assesses risk in further detail as it relates to these processes.

4.2 Understanding the Needs and Expectations of Interested Parties

We have identified and determined the requirements for the needs and expectations of our interested parties and their effect, or potential effect, on our organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements for our QMS. Below is a table identifying the most significant interested parties.

Interested Party	**Requirement**	**QMS Process**
Customer	Delivery, Quality, and Price	All Processes of our QMS
Suppliers	Delivery, Quality, and Price	Purchasing, Design & Development, Contract Negotiation, Incoming Inspection, Accounting, etc.
Employees	Benefits, Pay, Stability, Work Environment, Profit Sharing	Human Resources, Accounting, Training, Corporate Management, Maintenance, etc.
Owners	Profitability, Loyalty, Compliance to Lee Company Requirements	All Processes of our QMS
Community	Employment	All Processes of our QMS
Government	Taxes	All Processes of our QMS

4.3 Determining the Scope of the Quality Management System

4.3.1 Boundaries and Applicability

We have determined the boundaries and applicability of our QMS scope considering external and internal issues (see section 4.1), requirements of these parties, and our products and services.

4.3.2 Scope

This manual contains general descriptions of the components of our QMS and how it applies to risk, product and process quality, customer satisfaction, and ongoing improvement. Supporting documents, referenced in sections of this manual, provide more specific guidance to quality related activities. The ISO 9001:2015 QMS Standard and IATF 16949:2016 Automotive QMS Standard and applicable customer requirements provide specific guidance to the structure and requirements of our QMS; therefore, the organization of our Quality Manual is based on the organization of the ISO 9001 Standard and IATF 16949.

The Lee Company IMH Group scope is the design, development, and manufacturing of microhydraulic control components.

4.3.3 Not Applicable

The Lee Company IMH Group claims no exclusions (i.e. not applicable). It may however in some instances indicate if a pertinent sub-clause or sentence may not be applicable at this time.

4.4 Quality Management System and its Processes

4.4.1 Quality Management System and its Processes

a) Our QMS is designed to meet the requirements of the ISO 9001:2015 QMS Standard, IATF 16949:2016 Automotive QMS Standard, and customer specific requirements, when contractually obligated, as well as our interested parties both internal and external.

   Our QMS is what we do to implement our quality policy and objectives. It consists of the organizational structure, responsibilities, processes, documentation, and resources that enable us to manage the inputs and outputs of our processes. The goal of our QMS is to ensure that our products satisfy established requirements, meet or exceed our customer expectations and ultimately yield a profit. The QMS ensures that our products conform to those requirements and minimizes risk for all interested parties. The application of all our processes is generically defined in this The Lee Company IMH Group Quality Manual.

b) The sequence and interaction is defined throughout The Lee Company IMH Group Quality Manual. A high level process flow of our QMS identifying our processes and interactions of those processes is defined in the QMS Process Flow (see Section 4.4.2). More detailed processes, sequences and interactions are further identified through our procedures, process maps, work instructions, forms, records, software, and other means of documented information and communication.

c) Criteria and methods are needed to ensure that both the operation and management of these processes is effective. They are defined in QSP 1.4- Management Review, QSP 1.19 - Internal Audit, QSP 1.22 - Corrective Action, and QSP 1.24 - Risk Management, as well as Quality Objectives and numerous management metrics monitoring processes.

d) Management determines the amount and type of resources necessary to achieve our Quality Objectives then ensures resources are available, adequate, training provided where required, and fully supported. This is further detailed in part in the QSP 1.4- Management Review as well as other processes and procedures.

e) Responsibilities and authorities are defined throughout this document as well as in our systems, procedures, forms, etc. as well as in our QSP 1.3 - Management Responsibility. We also define our responsibilities through job descriptions and training plans. In addition, we communicate this information on a daily basis.

f) Risk is associated with every process in our QMS. As such we address risk in each respective process as well as documented in our QSP 1.24 - Risk Management. From receipt of a purchase order to shipment of product, we intuitively and/or objectively assess risk (see Section 6.1).

g) Quality objectives and metrics that measure and analyze our processes are monitored by management to ensure they meet anticipated requirements. Portions of these metrics are identified in QSP 1.4-Management Review. Additional metrics are created, monitored, and analyzed as required. Actions are taken when planned results or continual improvement of these processes are not met.

4.4.1.1 Conformance of Products and Processes

The IMH Group ensures conformance of all products and services, including those that are outsourced, to all applicable customer and legal requirements (see Section 8.4.2.2) and QSP 1.11 - Purchasing.

4.4.1.2 Product Safety

Within our documented processes we address product-safety related products and manufacturing processes, which includes but is not limited to the following, where applicable:

a) identification of any legal product-safety requirements;

b) customer notification of requirements concerning identification of any legal product-safety requirements;

c) special approvals for design FMEAs;

d) identification of product-safety related characteristics;

e) identification and controls of safety-related characteristics of product and at the point of manufacture;

f) special approval of control plans and process FMEAs;

g) reaction plans (see Section 9.1.1.1);

h) defined responsibilities, definitions of escalation process and flow down information, including top management, and customer notification;

i) training identified by the IMH Group or customer for personnel involved in product-safety related products and associated manufacturing processes;

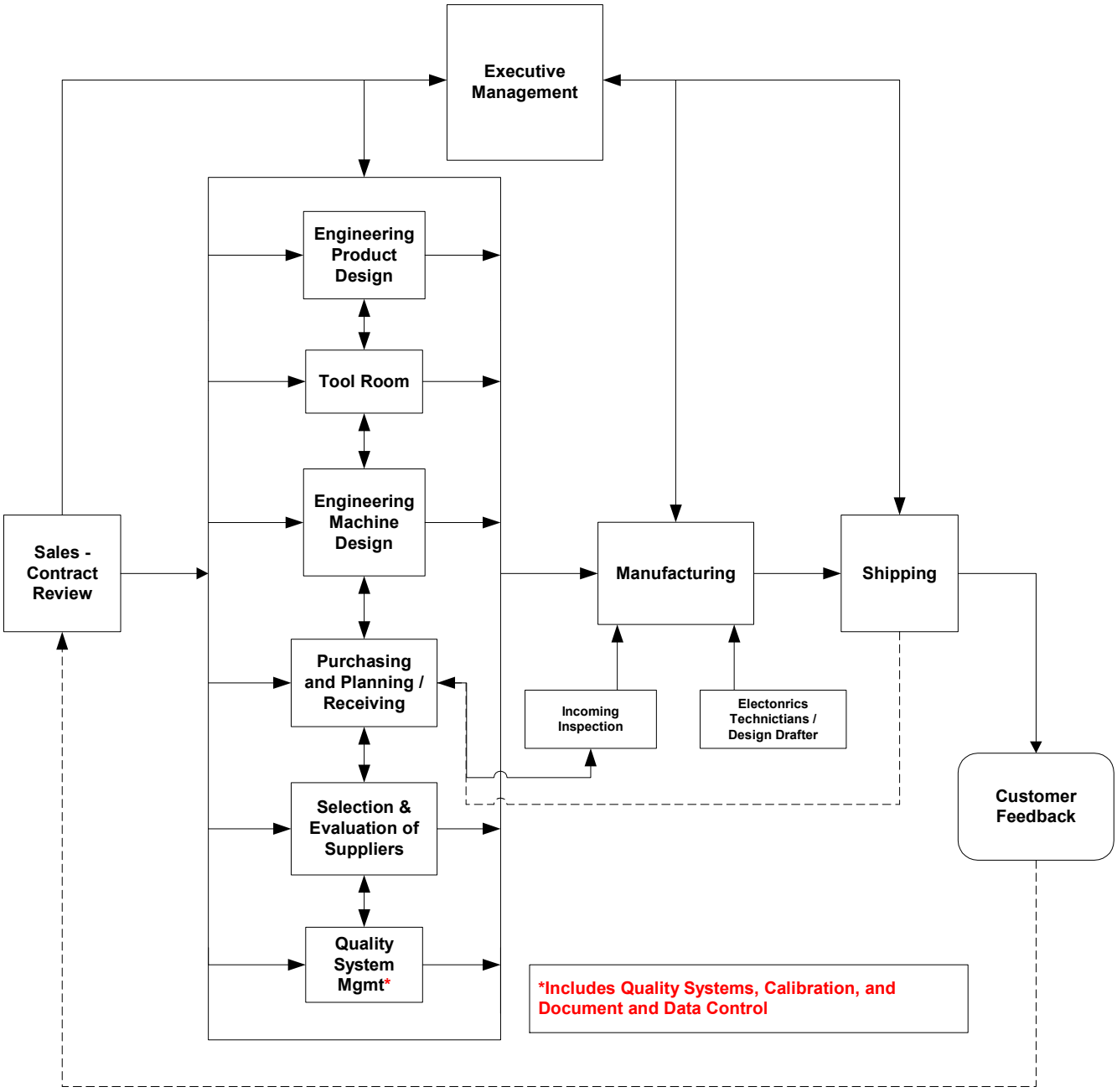
j) changes to product or processes approved prior to implementation, including evaluation of potential effects on product safety from process and product change (see Section 8.3.6);

k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (see Section 8.4.3.1);

l) product traceability by manufactured lot (at a minimum) throughout the supply chain (see Section 8.5.2.1);

m) lessons learned for new product introduction.

4.4.2 Quality Management System Process Flow



5.0 Leadership

5.1 Leadership and Commitment

5.1.1 General

Management has the responsibility to demonstrate leadership and commitment with respect to our QMS in communicating our Quality Policy, Quality Objectives, priorities, and to review and improve the QMS. Clearly defined management responsibility for our system is necessary to ensure the ongoing suitability and effectiveness of our QMS. Reference QSP 1.3 - Management Responsibility.

a) Management takes accountability for the effectiveness of the QMS. We do this by taking an active role in our QMS. One of the key tools is our Management Reviews.

b) We have reviewed and ensured that the Quality Policy and Quality Objectives are established for the QMS and are compatible with the context and strategic direction of the IMH Group.

c) Our QMS is how we manage our business. As a result, our QMS requirements are integrated into the organization's business processes.

d) We promote the use of the process approach by looking at all of our processes as defined in Section 4.4.2 including the inputs, outputs, resources, monitoring, measurement, improvement, training, and other considerations. Our philosophy is to take a proactive approach and be as efficient as possible. This is risk-based thinking.

e) Management ensures resources are available by the following methods:
- Budgets: Management establishes budgets for resources, capital, and expenses. Variances are monitored and reviewed, and budgets are adjusted appropriately.
- Management Review (QSP 1.4- Management Review): As a result of the Management Reviews, resources may be identified.
- Changes in Business: If changes in business occur, resources are reviewed, and actions are taken to address the business needs.

f) Management communicates the importance of effective quality and a conforming QMS through daily interaction, meetings, Product Development Team (PDT) meetings, Management Reviews, etc.

g) We ensure that the QMS achieves its intended results through internal audits, Quality Objectives, Management Reviews, and ultimately profit.

h) We foster employee involvement with our QMS by having employees actively involved. This engaging activity directly shows how we enable our employees to contribute to the effectiveness of the QMS. This in part is performed through daily conversation, meetings, and Manufacturing Meetings.

i) We as management encourage continuous improvement as identified in our Quality Policy (see Section 5.2). We also are involved directly in these improvement activities.

j) We support our management and supervisors by assisting them with their needs and by supporting their solutions and actions.

5.1.1.1 Corporate Responsibility

We define our corporate responsibilities on our web-site and/or handbook including at a minimum anti-bribery, code of conduct, ethics escalation, etc. This is defined under the Lee Company Standard Certifications, Employee Handbook, Ethics Policy, and Code of Conduct.

5.1.1.2 Process Effectiveness and Efficiency

Top Management Reviews product realization processes and supports processes to evaluate and improve their effectiveness and efficiency. The results of the process review are included as an input to our Management Reviews (see Section 9.3.2.1).

5.1.1.3 Process Owners

Top management has identified the process owners on the organizational chart, process maps, and relevant maintained documented information i.e. Quality Manual, procedures, etc. (see Section 7.2).

5.1.2 Customer Focus

Management demonstrates leadership and commitment with respect to customer focus by:

a) Ensuring customer requirements including statutory and regulatory (legal) are determined, understood, and are met by the following:
   - Direct communication with our customers.
   - Contract Review: QSP 1.6 - Customer-Related Processes and QSP 1.7 - Contract Review.
   - Metrics and Quality Objectives reviewed, and actions taken at our Management Review (QSP 1.4-Management Review).
   - Corrective Action (QSP 1.22 - Corrective Action).

b) Ensuring risks and opportunities that can affect our ability to supply product that meets our customer requirements with the aim of enhancing customer satisfaction through the following avenues:
   - Everyday risk-based thinking and QSP 1.24 - Risk Management.
   - Review of all Applications at our PDT meetings to assure we can meet said requirements.
   - Assuring adequate resources are available.
   - Looking at risks and opportunities as an input to our QSP 1.4- Management Review.
   - Supporting the internal audit program per our QSP 1.19 - Internal Audit and QSP 1.20 - Layered Process Audits.

c) Focusing on enhancing customer satisfaction:
   - Direct communication with our customers regarding their needs and expectations.
   - Customer feedback both positive and negative.
   - Utilization of our QMS.

5.2 Policy

5.2.1 Establishing a Quality Policy

The IMH Group's Quality Policy ensures that we comply with the requirements of IATF 16949. Our management system upholds high standards of quality, service, and on-time delivery, while protecting the environment and promoting the safety, education, and wellbeing of our employees. the IMH Group constantly improves our products, processes, systems, and services in order to satisfy all interested parties. Our strategic direction is to design and build state of the art products that exceed customers' expectations for utility, performance and quality. The formula for our Quality Policy is:

$(CE)^2$ = CONSTANTLY EXCEED CUSTOMER EXPECTATIONS

a) Management developed the Quality Policy in part to reinforce the purpose and context of our organization and to support the IMH Group's strategic direction.

b) The Quality Policy provides the framework for our Quality Objectives.

c) The Quality Policy includes a commitment to meet external, internal, and legal requirements.

d) The Quality Policy provides the commitment to strive to continually improve our QMS.

5.2.2 Communicating the Quality Policy

The Quality Policy:

a) The Quality Policy is controlled through our QSP 1.1 - Document & Data Control.

b) It is communicated for new employees during the orientation process. The Quality Policy is part of everyone's training plan. It is typically reviewed during performance appraisals. Additionally, refresher training is given to employees to ensure it is understood. The Quality Policy is posted and on the IMH Group online system (MCS). Finally, our personnel understand how they contribute to its success.

c) The Quality Policy is available as well to other interested parties as applicable.

5.3 Organizational Roles, Responsibilities and Authorities

Each person in the organization is responsible for understanding and adhering to the requirements of our QMS. Management has the responsibility to communicate our quality policy, objectives, priorities, responsibilities and authorities, and to review and improve the QMS.

An organizational chart is located on the last page of this manual.

Management Responsibility and Authority is defined within the Quality Manual, QSP 1.3 - Management Responsibility, associated procedures, and are communicated on a day-to-day basis.

Management:

- Strives to understand and meet customer expectations, utilizing continuous improvement processes.
- Establishes and communicate Quality Objectives and priorities.
- Communicates our Quality Policy through training and actions.
- Measures performance in meeting those expectations.
- Ensures that employees receive training specific to employees' areas of responsibility.
- Has responsibility for the integrity of documents and records appropriate to their areas of accountability.
- Advocates and support the prevention of quality problems through risk-based thinking and involvement in the corrective and preventive action processes.
- Participates in Management Reviews and is responsible for reporting on the performance of the QMS and need for improvement during the Management Review.
- Determines the amount and type of resources necessary to achieve Quality Objectives, and then makes sure the resources are available and training is provided where required.
- Ensures adequate resources are applied to training, internal audits, corrective action, and Management Reviews.
- Ensures personnel receive appropriate training so they can undertake their assigned responsibilities.

Non-Management employees' responsibilities are defined in job descriptions/training plans for each position and discussed at time of employment. Their job responsibilities and performance is reviewed at annual performance reviews and on a day-to-day basis.

Management has assigned a Management Representative who is also our Quality Assurance Manager. The Management Representative performs in part the following:

- Has the authority and responsibility to ensure that our QMS conforms to the ISO 9001:2015 QMS Standard, IATF 16949:2016 Automotive QMS Standard, and customer specific requirements when contractually obligated.
- Has the authority to host and represent management during second and third-party audits.
- Is responsible for the system that supports document control.
- Is responsible for providing training on assigned processes of the QMS.
- Ensures through the Management Review, internal audits, and other processes our QMS outputs are achieving the intended results.
- Ensures the promotion of awareness of customer requirements throughout the organization.
- Participates in the Management Reviews, the document control processes, and other means to ensure changes made to our QMS are appropriately planned and implemented.

Management ensures that the appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS. Internal communication lines are established by a variety of methods including:

- Management Reviews per the QSP 1.4- Management Review.
- Postings in cafeteria.
- The IMH Group online system postings.
- Online information systems including e-mail.
- The IMH Group Quality Manual, procedures, work instructions, forms, records, and other types of documented information.
- Software systems.
- Training.
- Meetings (various).
- Daily oral communication.
- "Send Word Now".

5.3.1 Organizational Roles, Responsibilities, and Authorities

Top management has assigned personnel with the responsibility and authority to ensure that customer requirements are met. These assignments are documented here or in the respective processes/procedures and other additional documented information. This includes but is not limited to the selection of special characteristics, setting Quality Objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards, and customer portals.

5.3.2 Responsibility and Authority for Product Requirements and Corrective Actions

Top management has ensured that:

a) Anyone has the authority to stop shipment and stop production to correct quality problems which affect conformity requirements.

b) Employees with authority and responsibility for corrective action are promptly informed of products or processes that do not conform to requirements to ensure that nonconforming product is not shipped to the customer and that all potential nonconforming product is identified and contained (reference QSP 1.21 - Control of Nonconforming Product).

c) Production operations across all shifts are staffed with supervisors with the responsibility for ensuring conformity to product requirements.

6.0 Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 Our planning for our QMS takes into consideration understanding our organization and its context (see Section 4.1) and the needs and expectations of our interested parties (see Section 4.2) as well as determines risk and opportunities. We assess risk and opportunities using various processes as well as inherently in everything we do. Some of our risk tools are FMEAs, APQP, DFM, etc. The following summarizes our approach to risk and opportunities:

a) We determine that our QMS can achieve its intended results through our Quality Objectives, Management Reviews, internal audits, and within all our processes. We have defined four key processes**:** (Contracts) QSP 1.6 - Customer-Related Processes and QSP 1.7 – Contract Review, (Design and Development) QSP 1.9 - Design and Development, (Purchasing) QSP 1.11 - Purchasing, and (Production) QSP 1.13 - Production & Service Provision which respectively address the risks associated within each process. In addition, all other processes identify the impact/risk on our business and customers both internally and externally. We address this in part in our QSP 1.24 - Risk Management.

b) Note that the output of all our processes is intended to achieve our planned results.

c) By assessing risk as identified above we expect to eliminate or reduce unintended results.

d) Through defining the aforementioned, we strive to drive continuous improvement throughout the IMH Group.

6.1.2 Risks will be addressed by process and on an individual basis. Whether it is a FMEA or simply not accepting a Purchase Order, these are all activities which determine risks and opportunities. In some circumstances a business decision may be to accept the risk.

a) We have integrated our risk assessment (risk-based thinking) into our processes and generically define how we will address any associated risk and opportunities throughout our processes. The following are some areas within our QMS that affect risk:
   - Context of Organization
   - Expectation of Interested Parties
   - Corrective Action
   - Analysis of Data
   - Management Review
   - Leadership
   - Customer Focus and Expectations
   - Design and Development
   - All of our Processes

b) By integrating our risk assessment into our processes, this enables us to assess the effectiveness associated with the specific process. Our process maps assist us in assessing the process characteristics such as inputs, outputs (expectations), criteria (metrics) and other high-level information to assist in the effective execution and improvement of our processes.

In summary, whether we choose to eliminate, reduce, change, share, avoid, or accept any risk or opportunity, this choice is primarily determined by the impact to our business. As such, less important issues will require less need for action.

6.1.2.1 Risk Analysis

We include in our risk analysis, at a minimum, lessons learned from product recalls, product audits, customer returns, complaints, scrap, level IV (high risk) applications etc.

6.1.2.2 Preventive Action

The IMH Group determines and implement action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the severity of the potential issues. We have established a process/procedure to lessen the impact of negative effects of risk including the following:

a) determining potential nonconformities and their causes;

b) evaluating the need for action to prevent occurrence of nonconformities;

c) determining and implementing action needed;

d) documented information of action taken;

e) reviewing the effectiveness of the preventive action taken and;

f) utilizing lessons learned to prevent recurrence in similar processes (see Section 7.1.6).

Reference QSP 1.23 - Preventive Action and Continual Improvement Procedure.

6.1.2.3 Contingency Plans

The IMH Group Contingency Plans (IMH Contingency Plan QSWI 9.18 and Contingency Plan for Suppliers QSWI 9.19) include:

a) identification and evaluation of both internal and external risks to all of our manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that the customer requirements are met;

b) define plans according to risk and impact to the customer;

c) prepare such contingency plans for continuity of supply in the event of any of the following: key equipment failures; interruption from externally provided products, processes, and services (suppliers); recurring natural disasters; fire; utility interruptions; labor shortages; or infrastructure disruptions;

d) include, as a supplemental to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting operations;

e) periodically test the contingency plans for effectiveness (e.g., simulations, as appropriate);

f) conduct contingency plan reviews (at minimum annually) using a multidiscipline team including top management and updated as required. Reference QSP 1.4- Management Review and;

g) document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the changes(s).

The contingency plans include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped, or if the regular shutdown processes were not followed. All our Quality System Work Instructions (QSWIs) are also reviewed by management.

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 We have established our Quality Objectives. Our Quality Objectives are consistent with the Quality Policy, measurable with goals, addressing applicable requirements, achieving conformity to product requirements while enhancing customer satisfaction. These objectives are monitored, communicated, and updated appropriately. Our Quality Objectives are available for all employees and interested parties to see.

6.2.2 We monitor these objectives during our Management Reviews (QSP 1.4- Management Review) to ensure we are meeting these goals and understanding the associated trends. We assess and determine if any necessary actions or resources are needed at our Management Review. Actions identify who is responsible, timeframe for completion, and evaluation of results. We also utilize other meetings in addressing our Quality Objectives and metrics.

6.2.2.1 Our top management ensures that Quality Objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization. This is primarily part of our Management Reviews. Reference QSP 1.4- Management Review.

The results of the organization's review regarding interested parties and their relevant requirements are considered when we establish our annual (at a minimum) Quality Objectives and related performance targets (internal and external) review.

6.3 Planning of Changes

Management ensures that the planning of the QMS meets the requirements and Quality Objectives described in this Quality Manual. Management identifies the purpose for these changes and assesses any potential consequences directly or indirectly. In addition, management ensures that the integrity of the QMS is maintained when changes are planned and implemented, resources are addressed, and responsibilities and authorities are identified.

The planning of the QMS is carried out in order to meet Quality Objectives and the requirements given in Section 4.4 of this Quality Manual. The integrity and changes to the QMS are primarily maintained through the QSP 1.4- Management Review and management meetings. Our QMS is documented information and changes that are controlled as detailed in QSP 1.1 - Document & Data Control as well as other procedures, work instructions, software systems, etc.

7.0 Support

7.1 Resources

7.1.1 General

We provide the necessary resources needed for the establishment, implementation, maintenance, and continual improvement of the QMS as defined in Section 5 through our budgetary process based on business needs, as well as Management Reviews. We consider our internal capabilities and constraints as well as suppliers.

7.1.2 People

We have determined and provided the persons necessary for the effective implementation of The Lee Company Industrial Microhydraulics Group QMS and for the operation and control of its processes.

7.1.3 Infrastructure

We provide an infrastructure that ensures conformance to product requirements. This includes but is not limited to buildings, workspace, utilities, process equipment (both hardware and software) including maintenance, and supporting services (such as transportation, communication, or information systems). In addition, the working environment needed to achieve conformity of product requirements is determined and managed appropriately. Some of the methods for determining infrastructure are performed in part by business profit, QMS planning, meetings, safety, analysis of data, feedback from interested parties, and internal audits. Preventive maintenance on equipment is performed in accordance with the preventive maintenance documented requirements (e.g. FASTMAINT, software back-up protocol, Contingency Plans, etc.) and other pertinent documents for safety, cleanliness, etc.

7.1.3.1 Plant, Facility, and Equipment Planning

Our management team uses a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans as a portion of the Planning Meeting. In designing plant layouts, we:

a) optimize material flow, material handling, and value-added use of floor space including control of nonconforming product, and

b) facilitate synchronous material flow, as applicable.

Methods are developed and implemented to evaluate manufacturing feasibility for new product or new operations. Manufacturing feasibility assessments shall include capacity planning. These methods are also applicable for evaluating proposed changes to existing operations. This is a large part of our Continuous Improvement Projects (CIPs).

We maintain process effectiveness, including periodic re-evaluation relative to risk, to incorporate any changes made during process approval, control plan maintenance (see Section 8.5.1.1), and verification of job set-ups (see Section 8.5.1.3).

Assessments of manufacturing feasibility and evaluation of capacity planning are inputs to Management Reviews (see Section 9.3).

7.1.4 Environment for the Operation of Processes

We provide a work environment that ensures conformance to product requirements. the IMH Group is a company where management supports communication and working together. We support a non-discriminatory, socially attractive, and non-confrontational environment. We strive to create a work environment that encourages respect, honesty, and integrity. Our facility provides adequate safety, lighting, temperature, humidity, noise, and cleanliness as defined above in Section 7.1.3. We abide by all applicable Connecticut State and Federal Labor Laws.

7.1.4.1 Environment for the Operation of Processes

Our premises are maintained so that they remain orderly and clean. Maintenance is performed to ensure consistency of product and process requirements.

7.1.5 Monitoring and Measuring of Resources

7.1.5.1 General

Inspection, measuring, and test equipment that is directly or indirectly used to determine product or material quality is controlled, calibrated, verified, and maintained to ensure it is accurate and appropriate for its intended use.

QSP 1.18 - Control of Monitoring and Measuring Devices describes our process for controlling, calibrating/verifying, and maintaining in-house inspection, measuring, and test equipment so that its measurement capability is known and its use is consistent with the required measurement capability.

7.1.5.1.1 Measurement Systems Analysis

Statistical studies are conducted to analyze the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan. The analytical methods (i.e. Gage R & R, capability studies, metrology analysis, etc.) and acceptance criteria used conform to those in reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be used if approved by the customer.

Records of customer acceptance of alternative methods shall be retained along with results from alternative measurement systems analysis (see Section 9.1.1.1).

7.1.5.2 Measurement Traceability

Where necessary to ensure valid results, measuring and test equipment is:

a) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis for calibration or verification is recorded.

b) Adjusted or re-adjusted as necessary and identified to enable the calibration status to be determined.

c) Safeguarded from adjustments that would invalidate the measurement result.

d) Protected from damage and deterioration during handling, maintenance and storage.

In addition, we assess and record the validity of the previous measuring results when equipment is found not to conform to requirements. Appropriate action is taken to bring the equipment and any affected product into conformity. The results of the calibration and verification is recorded and maintained (see Section 7.5).

When computer software is used in the monitoring and measurement of specified requirements, the ability of the software to satisfy the intended application is confirmed. This is undertaken prior to initial use and confirmed as necessary.

7.1.5.2.1 Calibration/Verification Records

We have a documented process QSP 1.18 - Control of Monitoring and Measuring Devices for managing calibration/verification records. Records of the calibration/verification activity for all measuring and test equipment (including employee-owned equipment relevant for measuring, customer-owned equipment, or on-site supplier-owned equipment) needed to provide evidence of conformity to internal requirements, legislative and regulatory requirements, and customer-defined requirements are retained in accordance with our QSP 1.2 - Quality Records.

The IMH Group ensures that calibration/verification activities and records shall include the following details:

a) revisions following engineering changes that impact measurement systems are included in the Control Plan;

b) any out-of-specification readings as received for calibration/verification;

c) an assessment of the risk of the intended use of the product caused by the out-of-specification condition;

d) when a piece of inspection measurement and test equipment is found to be out of calibration or defective during its planned verification or calibration or during its use, documented information on the validity of previous measurement results are obtained with this piece of inspection measurement and test equipment will be retained, including the associated standard's last calibration date and the next due date on the calibration report;

e) notification to the customer if suspect product has been shipped;

f) statements of conformity to specification after calibration/verification;

g) verification that the software version used for product and process control is as specified;

h) records of the calibration and maintenance activities for all equipment (including employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment);

i) production-related software verification used for product and process control (including software installed on employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment) as applicable.

7.1.5.3 Laboratory Requirements

7.1.5.3.1 Internal Laboratory

Our internal laboratory has a defined scope (see Calibration Laboratory QSWI 10.9) that includes its capability to perform the required inspection, test, or calibration services. This area specifies and implements, as a minimum, requirements for:

a) adequate technical procedures (QSWIs);

b) competency of the laboratory personnel as defined in our Training Tracker software;

c) testing of the product (where applicable);

d) capability to perform these services correctly, traceable to NIST or international standards; when no standard(s) are available, we will define and implement a methodology to verify measurement system capability;

e) customer requirements if any;

f) retained documented information (records) in accordance with QSP 1.2 - Quality Records.

7.1.5.3.2 External Laboratory

External/commercial/independent laboratory facilities used for inspection, test, or calibration services by the IMH Group shall have a defined laboratory scope that includes the capability to perform the required inspection, test, or calibration, and either: the laboratory shall be accredited to ISO/IEC 17025 or national equivalent and include the relevant inspection, test, or calibration service in the scope of the accreditation (certificate); the certificate of calibration or test report shall include the mark of a national accreditation body; or there shall be evidence that the external laboratory is acceptable to the customer.

Calibration services may be performed by the equipment manufacturer when a qualified laboratory is not available for a given piece of equipment. In such cases, we will ensure that the requirements listed in Section 7.1.5.3.1 have been met.

Use of calibration services, other than by qualified (or customer accepted) laboratories, may be subject to government regulatory confirmation, if required.

7.1.6 Organizational Knowledge

We have determined the necessary knowledge for personnel to perform their responsibilities to achieve the intended result of our QMS through our current job descriptions, procedures, work instructions, forms, software systems, etc. This is based on personnel competency, experience, education, and training. We evaluate employee competency through the output of work of each employee, performance reviews, Management Reviews on a day-to-day basis.

We minimize our risk by incorporating our knowledge into our procedures, work instruction, software systems, etc. where significant risk would have an adverse effect on the ability of our resources to achieve planned results.

As a result of risk analysis, corrective action, Management Reviews, management meetings, analysis of data, etc. we are addressing changing needs and potential trends. At this time, we address how to determine, acquire, access, or maintain this knowledge primarily through QSP 1.5 – Training Competence and Awareness, documented information, (i.e. QSP 1.1 - Document & Data Control), and software systems (e.g. QCBD, SmarTeam, FASTMAINT, etc.) or external resources.

7.2 Competence

a) We determine the competency of each person within our organization through the output of their work, day-to-day interaction, performance reviews, Management Reviews as well as other means.

b) Each person who impacts our QMS must have appropriate education, training, and experience for the system to succeed. Our QMS depends completely on the people who work within it. Employees who work within the QMS are trained on both the general and the specific requirements of the QMS as it applies to them.

c) Evaluation of the effectiveness of actions taken is part of management's responsibility (see Section 5). This evaluation of effectiveness is communicated via periodic discussions with employees, QSP 1.5 – Training Competence and Awareness, performance reviews, informal reviews, Management Reviews, and management activities, etc.

d) Training and retraining records as well as pertinent records regarding the above are maintained for all employees in accordance with our QSP 1.2 - Quality Records.

7.2.1 Competence

QSP 1.5 – Training Competence and Awareness identifies training needs including awareness (see Section 7.3.1) and achieving competence of all personnel performing activities affecting conformity to product and process requirements. Personnel performing specific assigned tasks are qualified, as required, with particular attention to the satisfaction of customer requirements.

7.2.2 Competence – On-the-Job Training (OJT)

We provide on-the-job training (which includes customer requirements training if applicable) for personnel in any new or changed job description affecting conformity to quality requirements, internal requirements, regulatory or legislative requirements which includes temporary personnel. The level of detail required for on-the-job training is in line with the level of education the personnel possess and the complexity of the task(s) they are required to perform for their daily work. Persons whose work can affect quality are informed about the consequences of nonconformity to customer requirements.

7.2.3 Internal Auditor Competency

The IMH Group has documented a process to verify that internal auditors are competent, taking into account any customer-specific requirements as identified in our QSP 1.5 - Training Competence and Awareness. We maintain a list of qualified internal auditors.

Our QMS auditors, manufacturing process auditors, and product auditors demonstrate the following minimum competencies:

a) understanding of the automotive process approach for auditing, including risk-based thinking;

b) understanding of applicable customer-specific requirements;

c) understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;

d) understanding of applicable core tool requirements related to the scope of the audit;

e) understanding how to plan, conduct, report, and close out audit findings.

Additionally, manufacturing process auditors demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (i.e. FMEAs) and control plans. Product auditors demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity.

We provide training to achieve competency, and documented information is retained (records) to demonstrate the trainer's competency with the above requirements in Training QCBD. This process is further defined in our QSP.

Maintenance of and improvement in internal auditor competence is demonstrated through:

f) executing a minimum number of audits per year, as defined in the QSP 1.5 - Training Competence and Awareness; and

g) maintaining knowledge of relevant requirements based on internal changes (e.g., process technology, product technology) and external changes (e.g., ISO 9001, IATF 16949, core tools, and customer specific requirements).

7.2.4 Second-party Auditor Competency

We demonstrate the competence of the auditors undertaking the second-party audits. Second-party auditors meet customer specific requirements for auditor qualification and demonstrate the minimum following core competencies, including understanding of:

a) the automotive process approach to auditing, including risk-based thinking;

b) applicable customer and organization specific requirements;

c) applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;

d) applicable manufacturing process(es) to be audited, including FMEAs and control plans;

e) applicable core tool requirements related to the scope of the audit;

f) how to plan, conduct, prepare audit reports, and close out audit findings.

This process is also summarized in our QSP 1.5 - Training Competence and Awareness.

7.3 Awareness

Our employees are aware and understand the Quality Policy and Quality Objectives as they pertain to their responsibilities. They are made aware of their contribution as well as the implication for lack of contribution and its effect on our QMS.

7.3.1 Awareness

In addition, we assure our employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with nonconforming product. This is performed during orientation, Manufacturing Meetings, training plan in QCBD, during their performance reviews in many cases, and other means of communication.

7.3.2 Employee Motivation and Empowerment

We motivate employees to achieve Quality Objectives and make continual improvements. We promote quality and technological awareness, and we create an environment that promotes innovation by rewarding employees through our profit sharing, bonuses, employee gifts, and our “open door policy.”

7.4 Communication

Management ensures that the appropriate communication processes are established both internal and external to the organization and that communication takes place relevant to the QMS. These lines of communication are performed by a variety of methods according to what needs to be communicated, who is responsible, who needs to know, what is the most effective way to communicate the pertinent information and includes but is not limited to:

- Management Reviews per the QSP 1.4- Management Review.
- Postings in cafeteria.
- The IMH Group online system postings.
- Online information systems including e-mail.
- The IMH Group Quality Manual, procedures, work instructions, forms, records, and other types of documented information.
- Software systems.
- Training.
- Meetings (various).
- Daily oral communication.

7.5 Documented Information

7.5.1 General

Our QMS finds value in balancing our documented information and relying on the competency of our personnel. Our QMS's documented information not only meets the IATF 16949 Standard requirements but also meets our QMS requirements with respect to objectives and continuous improvement as defined in our Quality Policy.

Throughout this manual there is terminology utilized from the Standards relative to documents and records. Where it may state maintained documented information, we are simply referring to our Quality Manual, procedures, work instruction, etc. thus our documents. Where we may state retained documented information we are referring to our records that provide objective evidence and are primarily electronic.

Documented information describes and defines our QMS from general principles to specifics. Documentation is a primary component of the QMS that provides the basis for our actions and a means to control and improve our results. By controlling QMS documentation, we provide stability and continuity to the system and ensure the standardization of processes and activities that take place within the system.

a) Quality Policy and Quality Objectives
   Our Quality Policy is our overall commitment of the organization. Refer to Section 5.2 for this policy. The Quality Objectives are documented and reviewed as part of the Management Review. Reference QSP 1.4- Management Review.

b) Quality Manual
The IMH Group Quality Manual contains an overall description of our QMS. It identifies the documented processes established by making reference to them in the manual's pertinent Sections. It provides the sequence and interaction (inputs and outputs) (see Section 4.4.2) including control of outsourced processes. This manual includes customer specific requirements within the relevant Sections as appropriate. The manual's focus is on interactions and intent, and it helps employees, customers, and suppliers understand our business approach.

c) Quality System Procedures
Quality System Procedures (QSPs) describes the QMS processes in more specific terms than the IMH Group Quality Manual.

d) Quality System Work Instructions
Quality System Work Instructions (QSWIs) are detailed documents that describe a process or sub-process in a detailed manner in a step by step approach. This documented information is more detailed than our Quality Manual and QSPs.

e) Forms and Records
Forms and records are used to input and retain information important to product quality. Their focus is on the inputs and outputs of our processes. Reference QSP 1.2 - Quality Records.

Each of the above documents has a clearly identified ownership in our document management software. The owner is responsible for determining the document's usefulness, completeness, usability, and accuracy. Additionally, we have other forms of documented information in the software systems we use (e.g. SmarTeam, FASTMAINT, QCBD, etc.)

7.5.2 Creating and Updating

We create and update our documented information (documents and records) through the use of our QSP 1.1 - Document & Data Control, QSP 1.2 - Quality Records, Software Machine, Software Revision, Installation, Verification, and Approval Instruction (QSWI 5.8), and QSP 1.9 – Design and Development. These processes identify and describe where applicable, format, review, and approval for suitability and accuracy of documented information.

7.5.3 Control of Documented Information

7.5.3.1 The QMS documents and records are available at points of use (computers) and are adequately protected in accordance with Section 7.5.2 procedures.

7.5.3.2 We control our documents and records as it relates to distribution, retrieval, use, storage, preservation, legibility, changes, retention, and disposition as defined utilizing the processes and procedures defined in Section 7.5.2.

Documents of external origin (various types of standards) are identified and controlled in accordance with our QSP 1.1 - Document & Data Control.

Our records are retained as evidence of conformity and protected from unintended alteration in accordance with our QSP 1.2 - Quality Records. In addition, our software systems have security in place and are backed up in accordance with our electronic back-up protocol.

7.5.3.2.1 Record Retention

Our record retention policy for the control of records that satisfy legal, organizational, and customer requirements (including PPAPs, tooling records, product and process design records, contracts and amendments) are retained for the length of time that the product is active for production and service requirements, plus one calendar year, unless otherwise specified by the customer or regulatory agency. This is further defined in our QSP 1.2 - Quality Records table.

7.5.3.2.2 Engineering Specifications

Our QSP 1.1 - Document & Data Control describes the review, distribution, and implementation of all customer engineering standards/specifications and related revisions based on customer schedules, as required.

For engineering standard/specification changes that result in a product design change refer to the requirements in QSP 1.9 – Design and Development and Section 8.3.6. For engineering standard/specification changes that result in a product realization process change refer to the requirements in Section 8.5.6.1. We retain a record of the date on which each change is implemented in production. Implementation includes updated documents. Note: Reviews should be completed within 10 working days of receipt of notification of engineering standards/specifications changes.

8.0 Operation

8.1 Operational Planning and Control

The organization plans, implements, and controls the processes (see Section 4.4) needed to meet the requirements for products, and implements the actions determined in Section 6. When planning, whether in a particular process, or more on a strategic level, we apply risk-based thinking in everything we do. We perform this in part in our Management Reviews and through the following actions:

a) Determining the requirements for products through our contract review process (see Section 8.2.2), design and development process (see Section 8.3), and our process development processes.

b) We establish the criteria for these processes (see Section 4.4) and acceptance of products through various types of inspection and through our QSP 1.13 - Production and Service Provision.

c) We have determined the resources needed to achieve product conformity (see Section 4.4).

d) We control our processes in accordance with defined criteria through management, measuring the output of these processes along with our Quality Objectives, inspection, etc. (see Section 4.4).

e) We determine, maintain, and retain our documented information (i.e. documents and records) to the extent defined to ensure our processes meet our expectations and demonstrate conformity to our requirements.

The output of this planning is our production documentation and systems. When we make changes to the aforementioned, it is performed in accordance with these documents as well as the QSP 1.1 - Document & Data Control and subsequent procedure(s).

See Section 8.4 for outsourced process otherwise known as suppliers.

8.1.1 Operational Planning and Control

When planning for production we include customer product requirements, logistics requirements, manufacturing feasibility, project planning (see Section 8.3.2), and acceptance criteria. Our requirements are covered in our Advanced Product Quality Planning (APQP) process in SmarTeam.

8.1.2 Confidentiality

We ensure confidentiality of customer products, projects under development, including related information.

8.2 Requirement for Product and Services

8.2.1 Customer Communication

a) The primary communication channels with our customers to discuss product information is through our Sales force, e-mail, verbal communications, our website, trade shows, product catalogs, product data sheets, and advertising.

b) Application sheets, inquiries, requests for quote, received purchase orders (including changes), etc. are handled in accordance with our QSP 1.6 – Customer Related Processes, QSP 1.7 – Contract Review Procedure, and QSP 1.8 - Customer Communication (Related Requirements on Web Sites) Procedure.

c) Customer feedback and complaints are received primarily through Sales and Management. Other employees are involved as necessary. Customer complaints may be processed through QSP 1.22 - Corrective Action Procedure and QSWI 14.4 - Customer Complaint Cycle (RMA's) Instructions.

d) Handling and controlling customer property is communicated and performed in accordance with Section 8.5.3 and in accordance with our QSP 1.17 - Customer Supplied Property.

e) As part of our risk-based thinking we may establish specific requirements for contingency actions/plans, when risk is significant and pertinent.

8.2.1.1 We communicate necessary information with our customers using agreed upon media.

8.2.2 Determining the Requirements for Products and Services

a) Initially, customer contact is primarily made via Sales or Order Entry (Customer Service). Customer requirements are communicated through direct conversation with the customer, drawings, application sheets, and purchase orders. Regulatory and statutory (legal) requirements related to product are identified; any additional requirements are taken into consideration.

b) During our review and risk assessment we ensure the IMH Group can meet our customer's requirements, expectations, and needs. In cases where the product was previously manufactured by the IMH Group, the customer requirements may be directly communicated to Customer Service through a purchase order. In other instances, it may be through an application sheet.

It is during this initial stage we hold periodic PDT meetings to assess the risk and severity of pursuing a particular inquiry/application. Applications are assessed and decisions are made based during this team review to determine what will be processed, actions to be taken, and risks to be eliminated, reduced, shared, or accepted.

8.2.2.1 Determining the Requirements for Products and Services

We will take into account recycling, environmental impact, and characteristics identified as a result of our knowledge of product and manufacturing processes. We also will assess all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

8.2.3 Review of Requirements for Products and Services

8.2.3.1 Customer requirements are reviewed using the QSP 1.7 - Contract Review. We also review requirements using a multidisciplinary approach through our PDT meetings as well as other forums. This process ensures our ability to meet all requirements.

a) Typical requirements include but are not limited to part number, quantity, delivery, and pricing, as well as terms and conditions.

b) Requirements not stated by the customer but necessary for specified and intended use, where known, will be communicated/reviewed.

c) Any internal requirements we may deem necessary for successful processing and obtaining customer satisfaction are assessed.

d) Statutory and regulatory (legal) requirements are reviewed as appropriate.

e) Any discrepancies are resolved before the purchase order is processed.

Where any product requirements are changed, we confirm these changes with the customer and the purchase order is amended. The amended purchase order and/or e-mail correspondence serves as evidence of the review or changes as well as our acknowledgement. The amended purchase order is communicated to necessary personnel in the organization.

When a customer provides no documented statement of requirements, requirements shall be confirmed via an acknowledgement before acceptance.

8.2.3.1.1 Review of Requirements for Products and Services

We will retain documented information (records) of customer-authorized waiver for requirements for formal review (see Section 8.2.3.1).

8.2.3.1.2 Customer-Designated Special Characteristics

The IMH Group will conform to customer requirements for designation, approval documentation, and control of special characteristics.

8.2.3.1.3 Organizational Manufacturing Feasibility

We utilize a multidisciplinary approach to conduct an analysis to determine if it is feasible that our manufacturing processes are capable of consistently producing product that meets all of the engineering and capacity requirements specified by the customer. We conduct this feasibility analysis for any manufacturing or product technology new to the organization and for any changed manufacturing process or product design. Such methodologies for organizational manufacturing feasibility are performed but not limited to FMEA, APQP, Cpk, SPC, Gage R & R, and Run @ Rate.

Additionally, we validate through production runs, benchmarking studies, or other appropriate methods to ensure our ability to make product to specifications at the required rate.

8.2.3.2 All records of these reviews including any new requirements or changes are maintained per QSP 1.2 - Quality Records.

8.2.4 Changes to Requirements for Products and Services

When changes are made, communication and appropriate documented information is processed in accordance with the above.

8.3 Design and Development of Products and Services

8.3.1 General

The organization has established, implemented, and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services as defined in our QSP 1.9 - Design and Development.

8.3.1.1 Design and Development

We apply design and development to both product and process. We focus our activities more on error prevention rather than detection.

8.3.2 Design and Development Planning

In determining the stages or phases and controls for design and development, the IMH Group has determined the following for our process:

a) We consider the extent of the design activity, the time it will take, as well as the complexity.

b) The stages/phases of our design and development process for product and process are as follows:
   - Application proposal through the SmarTeam database
   - Planning
   - Input
   - Output
   - Verification
   - Validation
   - Application release through the SmarTeam database
   - Lessons Learned

c) These stages above have design reviews as deemed necessary based on the scope and complexity of the project as outlined in our QSP 1.9 - Design and Development.

d) Responsibilities and authorities are identified in our QSP 1.9 - Design and Development. They're further defined in SmarTeam, Application Quality Plans, and other means of communication.

e) We consider any internal and external resource needs for the design and development of products, processes, and services.

f) Our design and development process of mature product is simplified. We assure those that require involvement in this process are appropriately communicated with and involved.

g) At times we will seek customer approval for our design and development activities. We involve the customers and users in the design and development process to the extent necessary to assure we meet all their requirements and expectations.

h) Any requirement for subsequent provisions of products, processes and services will be taken into consideration as applicable. This is not normally a part of our design and development process.

h) We control our design and development process in accordance with any and all contractual requirements and any other relevant interested parties. This is primarily accomplished at the planning stage when we obtain a new application.

i) We retain document information (i.e. records) for all the activities of our process as defined above in accordance with the QSP 1.2 - Quality Records.

8.3.2.1 Design and Development Planning

We ensure that the design and development planning include all affected stakeholders within our organization and, as appropriate, our supply chain. Using a multidisciplinary approach this includes but is not limited to the following:

a) project management (i.e. Advanced Product Quality Planning - APQP);

b) product and manufacturing process design activities (i.e. Design for Manufacturing - DFM, Design for Assembly - DFA);

c) development and review of product design risk analysis (i.e. Failure Mode and Effects Analysis - FMEAs), including actions to reduce potential risks and;

d) development and review of manufacturing process risk analysis (i.e. machine design reviews, FMEAs, process capability, control plans, Measurement Systems Analysis - MSA, work instructions).

8.3.2.2 Product Design Skills

We ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable product design tools and techniques. Applicable tools utilized include, but are not limited to, Design of Experiments – DOE and Computer Aided Design - CAD. Some of the core tools utilized include but are not limited to APQP and FMEA.

8.3.2.3 Development of Products with Imbedded Software

The organization currently does not use internally developed imbedded software, however if utilized we would develop a process including evaluation of risk.

8.3.3 Design and Development Inputs

The IMH Group determines the requirements essential for the specific types of products, processes, and services to be designed and developed. We consider the following as appropriate:

a) Functional and performance requirements.

b) Information derived from previous similar design and development activities.

c) Statutory and regulatory requirements.

d) Any procedures, work instructions, standards, etc. that we at the IMH Group are committed to implement.

e) We assess potential consequences of failure due to the nature of the products and services.

Inputs of the product are reviewed for adequacy as part of the design and development process. We assure any incomplete, conflicting, or unclear requirements are resolved during the input stage.

We retain documented information on design and development inputs in accordance with the QSP 1.9 - Design and Development and the QSP 1.2 - Quality Records.

8.3.3.1 Product Design Input

We identify, document, and review product design input requirements as a result of contract review. Product design input requirements include but are not limited to the following:

a) product specifications including but not limited to special characteristics (see Section 8.3.3.3);

b) boundary and interface requirements;

c) identification, traceability, and packaging;

d) consideration of design alternatives;

e) assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks, including from the feasibility analysis;

f) targets for conformity to product requirements including preservation, reliability, durability, serviceability, health, safety, environmental, development timing, and cost;

g) applicable statutory and regulatory requirements of the customer-identified country of destination, if provided and;

h) embedded software requirements (if applicable).

We use our SmarTeam software and other means to gather information gained from previous design projects, competitive product analysis (benchmarking), supplier feedback, internal input, customer data, and other relevant sources for current and future projects of a similar nature.

8.3.3.2 Manufacturing Process Design Input

We identify, document, and review manufacturing process design input requirements including but not limited to the following:

a) product design output data including special characteristics;

b) targets for productivity, process capability, timing, and cost;

c) manufacturing technology alternatives;

d) customer requirements, if any;

e) experience from previous developments;

f) new materials;

g) product handling and ergonomic requirements and;

h) Design for Manufacturing (DFM) and Design for Assembly (DFA).

The manufacturing process design includes the use of methods (e.g. DFM, DFA, error-proofing methods, automation, etc.) to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered.

8.3.3.3 Special Characteristics

We assign a Product Engineer with a design team to establish, document, and implement our process(es) to identify special characteristics, including those determined by the customer and the risk analysis performed by the organization, and shall include the following:

a) documentation of all special characteristics in the drawings (as required), risk analysis (i.e FMEA), control plans, and work instructions; special characteristics are identified with specific markings and are identified through each of these documents;

b) development of control and monitoring strategies for special characteristics of products and production processes;

c) customer-specified approvals, when required and;

d) compliance with customer-specified definitions and symbols or the organization's equivalent symbols or notations, as defined in a symbol conversion table. The symbol conversion table shall be submitted to the customer, if required.

8.3.4 Design and Development Controls

The IMH Group has applied controls to the design and development process to ensure that:

a) The results to be achieved are defined per the respective stages and associated design reviews.

b) Our design reviews are conducted to evaluate the ability of the results of design and development to meet our input requirements.

c) At verification we ensure that the design and development outputs meet the input requirements.

d) Validation is conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use as specified by the customer. Ultimately, in-service validation must be performed by our customers. We do perform some testing. However, this is limited. We include the validation activities and correspondence in the design and development process when performed or received.

e) Throughout our process any necessary actions are taken on problems determined during the reviews, or verification and validation activities.

f) We retain documented information of these activities in accordance with our procedures identified above.

8.3.4.1 Monitoring

A year end Engineering Review Summary is held once a year for management that analyzes and reports with summary results as an input to Management Review (see Section 9.3.2.1).

When required by the customer, measurements of the product and process development activity will be reported to the customer at stages specified or agreed to by the customer.

When appropriate, these measurements may include quality risks, costs, lead times, critical paths, and other measurements.

8.3.4.2 Design and Development Validation

Design and development validation is performed in accordance with customer requirements, including any applicable industry and governmental agency-issued regulatory standards. The timing of design and development validation is planned in alignment with customer-specified timing, as applicable.

Where contractually agreed with the customer, we will include evaluation of the interaction of the organization's product within the customer's system.

8.3.4.3 Prototypes

When required by the customer, we have a prototype program and control plan. We use, whenever possible, the same suppliers, tooling, and manufacturing processes that will be used in production.

All performance-testing activities are monitored for timely completion and conformity to requirements.

8.3.4.4 Product Part Approval Process (PPAP)

We have established, implemented, and continue to maintain a product and manufacturing approval process that conforms to requirements defined by the customer(s).

We approve externally provided products and services per Section 8.4.3 prior to submission of the part approval to the customer.

We obtain documented product approval prior to shipment, if required by the customer. Records of such approval shall be retained in accordance with our QSP 1.2 - Quality Records.

8.3.5 Design and Development Outputs

The IMH Group ensures that design and development outputs:

a) meet the input requirements as defined in our process;

b) are adequate for the subsequent processes for the provision of products and services;
c) include, or reference, monitoring and measuring requirements (as appropriate) and acceptance criteria. (this is primarily done through our drawings, control plans, and work instructions) and;

d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision. This is done primarily through our drawings and control plans.

We retain documented information on design and development outputs per the QSP 1.2 - Quality Records.

8.3.5.1 Design and Development Outputs

The product design outputs are expressed in terms that can be verified and validated against product design input requirements. The product design output includes but is not limited to the following, as applicable:

a) design risk analysis (FMEA);

b) reliability study results (cycle testing, performance testing, etc.);

c) product special characteristics;

d) results of product design error-proofing, Design for Manufacturing (DFM);

e) product definition;

f) drawings, work instructions, control plans;

g) product design review results and;

h) packaging and labeling requirements for shipping.

8.3.5.2 Manufacturing Process Design Output

We document the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. Then we verify the outputs against manufacturing process design input requirements. The manufacturing process design output shall include but is not limited to the following:

a) product definition

b) special characteristics for product and manufacturing process (if applicable);

c) identification of design process inputs that may impact characteristics;

d) tooling and equipment for production and control, including capability studies of equipment and process(es);

e) process flow through control plans;

f) capacity analysis;

g) PFMEAs;

h) maintenance plans and instructions in FASTMAINT;

i) control plans;

j) work instructions;

k) process approval acceptance criteria;

l) data for quality, reliability, maintainability, and measurability;

m) results of error-proofing identification and verification, as appropriate and;

n) methods of rapid detection, feedback, and correction of product/manufacturing process nonconformities through Early Production Containment (EPC).

8.3.6 Design and Development Changes

Work flows in our SmarTeam Engineering database are used to identify, review, and control changes made during, or subsequent to, the design and development of products, processes, and services. This is done to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

We keep records which include what is being changed, review of the change, identification of authorization for said change, and any actions taken to prevent any adverse effects on the product changes as defined in our QSP 1.9 - Design and Development.

8.3.6.1 Design and Development Changes

We evaluate all design changes after initial product approval, including those proposed by the organization or its suppliers, for potential impact on form, fit, function, performance, and/or durability. These changes shall be validated against customer requirements and approved internally, prior to production implementation.

If required by the customer, we obtain documented approval, or a documented waiver, from the customer prior to production implementation.

For products with embedded software, the organization shall document the revision level of software and hardware as part of the change record (if applicable).

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

Purchasing, Management, Quality, Engineering, Logistics, and Production work together to ensure that we receive an uninterrupted supply of material, products, and services from our suppliers that conforms to our requirements for quality, service, delivery, and safety at competitive prices. Reference our QSP 1.11 - Purchasing.

In accordance with the appropriate procedures, Purchasing procures material, products, and tooling from suppliers and receiving/receiving inspection verifies that the material, product, and tooling as well as the supplier meet our quality requirements as appropriate. Reference our QSP 1.11 - Purchasing.
Purchasing and Quality Assurance uses a controlled Approved Supplier system. The supplier criteria for evaluation, selection process, monitoring for performance, and re-evaluation is described in the QSP 1.11 - Purchasing. This procedure also defines how new suppliers are added as an Approved Supplier.

Records of this activity are maintained in accordance with our QSP 1.2 - Quality Records.

8.4.1.1 General

We include all products and services that affect customer requirements such as delivery, calibration, internal audit services in the scope of their definition of externally provided products, processes, and services.

8.4.1.2 Supplier Selection Process

We have a documented supplier selection process as identified in our QSP 1.11 - Purchasing. The selection process shall include:

a) an assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers;

b) relevant quality and delivery performance;

c) an evaluation of the supplier's QMS;

d) multidisciplinary decision making; and

e) an assessment of software development capabilities, if applicable.

Other supplier selection criteria that should be considered include the following: volume of automotive business (absolute and as a percentage of total business); financial stability; purchased product, material, or service complexity; required technology (product or process); adequacy of available resources (e.g., people, infrastructure); design and development capabilities (including project management); manufacturing capability; change management process; business continuity planning (e.g., disaster preparedness, contingency planning); logistics process; customer service, etc.

8.4.1.3 Customer-Designated Sources

When specified by the customer, we purchase products, materials, or services from customer-designated sources.

All requirements of Section 8.4 (except the requirements in IATF 16949, Section 8.4.1.2) are applicable to the control of customer-designated sources unless specific agreements are otherwise defined by the contract between us and the customer.

8.4.2 Type and Extent of Control

We ensure our suppliers do not affect our ability to supply product. As a result, we perform the following:

a) We ensure that they remain within the control of our QMS per QSP 1.11 - Purchasing.

b) We have established performance metrics for our suppliers. If they fail to meet our goals, there is a distinct process within our supplier management process we will follow up to and including disapproval. We monitor our suppliers to these metrics through observation, delivery, quality, etc. dependent upon the product or service provided.

c) In performing the above we assess the risk in meeting our customer's requirements and any statutory and regulatory (legal) requirements. We apply the necessary control dependent on the risk. We monitor the effectiveness through our metrics, processes, and actions.

d) We ensure our product meets specified requirements in accordance with our QSP 1.11 - Purchasing. If specified by our contracts, we have the right to verify purchased product at suppliers' premises. This does not absolve us of our responsibility to provide acceptable product, nor does it preclude possible rejection by the customer. For provided services (e.g. internal auditing, shipping, calibration services, etc.), we monitor their performance in meeting our needs through observation and results.

8.4.2.1 Type and Extent of Control

QSP 1.11 - Purchasing defines the process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal (organizational) and external customer requirements.

The process includes the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks.

8.4.2.2 Statutory and Regulatory Requirements

We also document and ensure that purchased products, processes, and services conform to the current applicable legal requirements in the United States, the country of shipment, and the customer-identified country of destination, if provided.

If our customer defines special controls for certain products with statutory and regulatory requirements, we ensure they are implemented and maintained as defined, including flowing down to our suppliers (as applicable).

8.4.2.3 Supplier Quality Management System Development

Supplier Management strives to have our suppliers to the extent possible, become certified to ISO 9001 and IATF 16949 in concert with requirements of TS16949:2016 Section 8.4.2.3. Unless otherwise specified by the customer, the following sequence is the methodology we use to achieve this requirement:

a) compliance to ISO 9001 through second-party audits;

b) certification to ISO 9001 through third-party audits; unless otherwise specified by the customer, suppliers to the IMH Group shall demonstrate conformity to ISO 9001 by maintaining a third-party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA (International Accreditation Forum Multilateral Recognition Arrangement) member and where the accreditation body's main scope includes management system certification to ISO/IEG 17021;

c) certification to ISO 9001 with compliance to other customer-defined QMS requirements such as Minimum Automotive QMS Requirements for Sub-Tier Suppliers (MAQMSR or equivalent) through second-party audits);

d) certification to ISO 9001 with compliance to IATF 16949 through second-party audits;

e) certification to IATF 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body).

8.4.2.3.1 Automotive Product-related Software or Automotive Products with Embedded Software

While this is currently not applicable, we would require their suppliers of automotive product-related software, or automotive products with embedded software, to implement and maintain a process for software quality assurance for their products.

A software development assessment methodology would be utilized to assess the supplier's software development process. Using prioritization based on risk and potential impact to the customer, we would require the supplier to retain documented information of a software development capability self-assessment.

8.4.2.4 Supplier Monitoring

Our QSP defines criteria to evaluate supplier performance in order to ensure conformity of externally provided products, processes, and services to internal and external customer requirements. We monitor delivery, quality, and other concerns in not meeting our requirements.

8.4.2.4.1 Second-Party Audits

We perform second-party audits based on risk, safety, legal, performance indicators, and other requirements and criteria deemed necessary as defined in our QSP 1.11 - Purchasing.

Based on the above we define in our QSP the criteria for determining the need, type, frequency, and scope of second-party audits.

We retain records of the second-party audit reports.

Note: Second-party audits that assess the supplier's QMS are consistent with the automotive process approach.

8.4.2.5 Supplier Development

Our Supplier Management determines the priority, type, extent, and timing of required supplier development actions for its active suppliers. Determination inputs shall include but are not limited to the following:

a) performance issues identified through supplier monitoring (see Section 8.4.2.4);

b) second-party audit findings (see Section 8.4.2.4.1);

c) third-party QMS certification status;

d) risk analysis.

Supplier Management implements actions necessary to resolve open (unsatisfactory) performance issues and pursue opportunities for continual improvement.

8.4.3 Information for External Providers

We communicate our requirements to our suppliers through purchase orders. Purchase orders are completed, reviewed, and approved for adequacy prior to submitting them to our suppliers.

We communicate the following requirements:

a) identifying the specific requirements such as description, price, delivery, etc;

b) additional approval requirements we may have or those that are imposed upon us (e.g. products, methods, processes, equipment, release of products and services, etc.);

c) any qualification requirements including competency;

d) identification of special communication requirements;

e) control and monitoring of suppliers to be applied by the IMH Group if applicable and;

f) inspection and/or validation activities we or our customer may want to perform at our supplier's premises if necessary.

8.4.3.1 Information for External Providers

We flow down any legal requirements or special process/product characteristics to our suppliers and consequently the sub-tier suppliers.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

The production process is carried out under controlled conditions, which govern the activities and equipment that directly affect product quality. Process control helps us reduce variability, produce consistent product, and ensure our products meet design specifications, customer needs, and statutory and regulatory (legal) requirements.

Engineering, Management, Manufacturing, Logistics, and Quality are responsible for planning production processes so that they are carried out under controlled conditions. These groups also document production processes and approve process changes. This process is further described in the QSP 1.13 - Production & Service Provision Procedure and QSP 1.14 – Control of Production & Service Provision Procedure as well as other processes (e.g. contract review, design and development, etc.).

Controlled conditions include the following as applicable dependent on the product:

a) our documented information such as procedures, work instructions, drawings, control plans, systems, etc. helps us control the process. Primarily, machine logs and verification logs along with our control plans show that results are achieved;

b) identification and use of calibrated or verified inspection equipment (see Section 7.1.5);

c) our control plans determine at what stages of the process we inspect product;

d) use of acceptable equipment in a suitable environment (see Sections, 8.1, 7.1.3 and 7.1.4);

e) competent people are utilized as defined (see Section 7.1);

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement (i.e. special processes);

g) every effort to remove human error through mistake proofing, automation, documented information (e.g. control plans, drawings, forms, checklists, etc.), and simplifying processes, etc. and;

h) release, delivery and (if applicable) post-delivery activities through our documented information including software systems.

Records are created as needed and provide evidence that the production processes and resulting product meet requirements.

8.5.1.1 Control Plan

We use control plans (in accordance with IATF 16949:2016 Annex A) for assembly, component, and/or material level for all product supplied, as well as parts. We generate a control plan for pre-launch and production that shows linkage and incorporates information from the design risk analysis, process flow diagram, and manufacturing process risk analysis outputs (such as FMEAs).

Our control plans used for manufacturing process control include verification of job set-ups (MCS), first piece validation (as applicable), special characteristics (as applicable), customer requirements (as applicable), and a process for when nonconforming product has made the process unstable (CATS).

Control plans are reviewed and updated accordingly when nonconforming product is sent to the customer; when changes occur that affect our product, the manufacturing process, measurements, logistics, supply sources, or production volumes, risk (FMEA); after implementation of corrective actions related to a customer complaint; or as required based on risk analysis.

8.5.1.2 Standardized Work - Work Instructions and Visual Standards

We have documented work instructions, visual aids, and control plans in MCS, OPACT, etc. that communicate to the operator the necessary work. Work stations are made available at these designated areas and assure legibility and are written such that employees can understand. Also, our documentation includes rules for operator safety.

8.5.1.3 Verification of Job Set-ups

We verify job set-ups thru the following:

a) verify job set-ups when performed, such as an initial run of a job, material changeover, or job per our set-up control plans, work instructions, and lot control rules;

b) change that requires a new set-up are controlled in MCS with machine logs;

c) maintain documented information for set-up personnel in MCS;

d) use statistical methods of verification, where applicable, such as sampling, SPC, etc.;

e) perform first piece validation, beginning of shift, end of shift, every two hours, etc. as applicable and;

f) retain records of process and product approval following set-up and various part validations.

8.5.1.4 Verification after Shutdown

We have defined and implemented the necessary actions to ensure product compliance with requirements after planned or unplanned production shutdown periods through our normal verifications and validations. Also, see Section 6.1.2.3.

8.5.1.5 Total Productive Maintenance

We have developed, implemented, and maintain a documented total productive maintenance system. The system at a minimum includes the following:

a) identification of process equipment necessary to produce conforming product at the required volume in FASTMAINT;

b) availability of replacement parts for the equipment identified in “spare parts” ERP;

c) adequate resources for machine, equipment, and facility maintenance;

d) packaging and preservation of equipment, tooling, and gauging;

e) applicable customer-specific requirements;

f) documented maintenance objectives;

g) regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;

h) use of preventive maintenance methods;

i) use of predictive maintenance methods, as applicable and;

j) periodic overhaul.

8.5.1.6 Management of Production Tooling and Manufacturing, Test, Inspection Tooling and Equipment

We provide resources for tool and gauge design, fabrication, and verification activities for production and service materials and for bulk materials, as applicable. We have established and implemented a system for production tooling management, whether owned by the IMH Group or the customer, including:

a) maintenance and repair facilities and personnel;

b) storage and recovery at machines;

c) set-up in accordance with our work instructions;

d) tool-change program in accordance with automation software;

e) tool design modification documentation (drawings), including engineering change level of the product in SmarTeam;

f) tool modification and revision to drawings in SmarTeam and;

g) tools are marked and storage locations identified in ERP. Customer owned tooling is marked in visible locations and handled in accordance with Section 8.5.3.

8.5.1.7 Production Scheduling

Production is scheduled in order to meet customer orders/demands such as Just-In-Time (JIT) and is supported by ERP and other information systems that permits access to production information at key stages of the process and is order driven.

We include relevant planning information during production scheduling (e.g., customer orders, supplier on-time delivery performance, capacity, lead time, inventory level, preventive maintenance, and calibration).

8.5.2 Identification and Traceability

Identifying our product to a specific part number and lot number using bar code labels is our primary means for traceability. Part numbers with revisions and descriptions are assigned to products. Each part number is tied directly to our product documentation (e.g., drawing, lot number, work order number, etc.) that defines the particular part. Where appropriate, individual parts are uniquely identified to enable traceability but primarily through the various labels supplied throughout the production process and delivered to our customer.

The verification of product ensures that only product that has been processed through the sequence label and machine logs and verification logs is shipped. The Manufacturing Manager and Supervisors along with the support staff have the overall responsibility for administering the system to assure product meets the requirements. Identification and traceability is further defined in QSP 1.15 - Product Identification & Traceability.

Inspection of product is primarily performed by operators identified using online signature, employee number, log on identification, stamps on labels, etc. which indicate the conformance or nonconformance of product with regard to sequences performed in accordance with control plans and other supporting documentation. The identification of verification is maintained, as necessary, throughout the production process to ensure that only product that has passed the required sequences on the sequence label and appropriate sign-offs on the machine logs and verification logs is shipped. Reference QSP 1.16 – Inspection & Test Status.

8.5.2.1 Identification and Traceability

The purpose of traceability is to support identification of clear start and stop points for product received by the customer that may contain quality and/or safety-related nonconformities. As a result, we have implemented identification and traceability process through our lot control and sample frequency quality checks.

We conduct an analysis of internal, customer, and regulatory traceability requirements for all automotive products, including developing and documenting traceability plans, based on the levels of risk or failure severity for employees, customers, and consumers. This is part of our QSP 1.15 - Product Identification & Traceability and QSP 1.16 – Inspection & Test Status. Note these plans define the appropriate traceability systems, processes, and methods by product, process, and manufacturing location that:

a) enable us to identify nonconforming and/or suspect product;

b) enable us to segregate nonconforming and/or suspect product;

c) ensure the ability to meet the customer and/or regulatory response time requirements;

d) ensure documented information is retained in the format (electronic, hardcopy, archive) that enables the organization to meet the response time requirements;

e) ensure serialized identification of individual products, if specified by the customer or regulatory standards;

f) ensure the identification and traceability requirements are extended to externally provided products with safety/regulatory characteristics.

8.5.3 Property Belonging to Customers or External Providers

Gaging or product provided by any customer for use or incorporation into finished product is identified, verified, stored, protected, and maintained. Any product that is lost, damaged, or is otherwise unsuitable for use shall be recorded and reported to the customer. Customer property at the IMH Group that is in the form of intellectual property such as drawings and specifications is also controlled. Reference our QSP 1.17 - Customer Supplied Property and this Quality Manual.

8.5.4 Preservation

We have a process for handling, storing, packaging, and delivering product so that our customers receive product in the same condition in which it was released from production.

The organization makes sure that customer orders are filled and shipped in accordance with purchase order requirements.

8.5.4.1 Preservation

Preservation also includes identification, handling, contamination control, transmission or transportation, and protection.

Preservation applies to all our materials and components from external and/or internal providers from receipt through processing, including shipment and until delivery to/acceptance by the customer.

In order to detect deterioration, we perform Cycle Counts to assess at appropriate planned intervals the condition of product in stock, the place/type of storage container, and the storage environment. We also perform periodic inspections in accordance with (QSWI 15.5) to assure no degradation, etc.

We maintain an inventory management system to optimize inventory turns over time and ensure stock rotation, such as "First-In-First-Out" (FIFO).

We ensure that obsolete and down-level product is identified and controlled like nonconforming product.

We comply with preservation, packaging, shipping, and labeling requirements as provided by our customers.

8.5.5 Post-Delivery Activities

We determine requirements for post-delivery activities associated with product. While we do not provide the traditional activities (e.g. maintenance, supplementary services, etc.), we may receive returned product or have a request for information or additional service after delivery that enables us to build and maintain long-term relationships.

In determining the extent of these post-delivery activities required, the organization takes into consideration (as applicable):

a) statutory and regulatory (legal) requirements;

b) potential problems with product;

c) application and life cycle (if applicable);

d) customer requirements and;

e) customer feedback.

Again, a majority of the above is not applicable but customer requirements and feedback will be appropriately determined.

8.5.5.1 Feedback of Information from Service

The IMH Group has established, implemented, and maintained a process for communication of information on service concerns to production, material handling, logistics, engineering, and design activities. These service concerns are to ensure we are aware of nonconforming product(s) and material(s) that may be identified at the customer location or in the field. Reference both QSP 1.21 - Control of Nonconforming Product and Customer Complaint Cycle (RMA's) Instructions (QSWI 14.4).

8.5.5.2 Service Agreement with Customer (Not Applicable)

If there was a service agreement with the customer, we would:

a) verify that the relevant service centers comply with applicable requirements;

b) verify the effectiveness of any special purpose tools or measurement equipment and;

c) ensure that all service personnel are trained in applicable requirements.

8.5.6 Control of Changes

Changes are controlled primarily through our QSP 1.1 - Document & Data Control and QSP 1.9 – Design and Development. This is performed to the extent necessary to ensure we meet requirements but also to improve efficiency, minimize risk including human error, and continuously improve.

8.5.6.1 Control of Changes

The IMH Group documents its processes to control and react to changes that impact product realization. The effects of any change, including those changes caused by the organization, the customer, or any supplier, are assessed. We define verification and validation activities to ensure compliance with customer requirements, validate changes before implementation, document the evidence of related risk analysis, and retain records of verification and validation.

Changes, including those made at our suppliers, should require a production trial run for verification of changes (such as changes to part design, manufacturing location, or production process) to validate the impact of any changes on the production process.

When required by the customer, the IMH Group will notify the customer of any planned production changes after the most recent product approval and obtain documented approval, prior to implementation of the change, and complete additional verification or identification requirements, such as production trial run and new product validation. Reference QSP 1.1 - Document & Data Control for document changes. Reference QSWI 5.8 - Software Machine, Software Revision, Installation, Verification, and Approval Instruction for

software changes. Reference QSP 1.9 – Design and Development, as well as the IMH Group work order system, for design and development changes in SmarTeam.

8.5.6.1.1 Temporary Change of Process Controls

The organization identifies, documents, and maintains a list of process controls including inspection, measuring, test, error-proofing, and back-up or alternative methods per QSWI 13.8 - Process for Use of Approved Alternate Process Controls and QSWI 13.81 - Approved List of Alternate Process Controls. Alternative methods may not be utilized but back-up methods are used to mitigate risk. Reference QSWI 9.18 - IMH Contingency Plan and see Section 6.1.2.3.

8.6 Release of Products and Services

Characteristics of the product are monitored and measured (inspection and test) in order to verify that product requirements have been met. This is carried out at appropriate stages of the production process in accordance with the planned arrangements utilizing our control plans, sequence labels, machine logs, and verification logs and other applicable documentation and systems. Reference QSP 1.13 – Production & Service Provisions, this manual, other pertinent procedures, work instructions, and software systems. Evidence of conformity with acceptance criteria is maintained. The sequence label, machine logs, and verification logs indicates the person(s) authorizing release of product.

Product shall not be released until all activities specified by the above and any other pertinent documented information have been satisfactorily completed and the required records are complete and authorized unless authorized in writing by management including customer authorization where applicable.

8.6.1 Release of Products and Services

Details of the Control Plan are specified in IATF 16949 Annex A.

8.6.2 Layout Inspection and Functional Testing

A layout inspection and a functional verification to applicable customer engineering material and performance standards may be performed utilizing Initial Sample Inspection Reports (ISIRs). This may be completed per the IMH Group and applicable customer requirements and are available for customer review.

8.6.3 Appearance Items (Not Applicable)

Should we manufacture product designated by the customer as "appearance items," we will provide the following:

a) appropriate resources, including lighting, for evaluation;

b) masters for color, grain, gloss, metallic brilliance, texture, distinctness of image (001), and haptic technology, as appropriate;

c) maintenance and control of appearance masters and evaluation equipment and;

d) verification that personnel making appearance evaluations are competent and qualified to do so.

8.6.4 Verification and Acceptance of Conformity of Externally Provided Products and Services

We verify all product provided by externally provided processes, products, and services through inspection evaluation, metrics, second & third-party assessments, etc. (see Section 8.4).

8.6.5 Statutory and Regulatory Conformity

We comply with all legal requirements (e.g. REACH, EAR, RoHs, Conflict Minerals, etc.) and legal requirements imposed by the country of destination if known.

8.6.6 Acceptance Criteria

Acceptance criteria is defined in our control plans, drawings, etc. and, where appropriate or required, approved by the customer. For attribute data sampling, the acceptance level shall be zero defects (see Section 9.1.1.1).

8.7 Control of Nonconforming Outputs

8.7.1

The IMH Group identifies and controls material or product that does not meet our requirements so we can avoid mixing it with material or product that will be shipped to our customers. QSP 1.21 - Control of Nonconforming Product is the procedure that identifies the segregation, identification, and authority required. In addition, by recording the circumstances around the nonconformance, we are able to take appropriate action as described in Section 10.2.

Material/Product that does not conform to our specified requirements is identified, verified, inspected, and tested during various stages of production. After being identified, nonconforming material is segregated from conforming product.

Management, Quality, Engineering, Purchasing or Manufacturing are responsible for reviewing the nonconforming material and determining its' disposition. Disposition authority is further detailed in the procedure. Reworked product is re-inspected as necessary to meet specified requirements. Product that may be use-as-is or repaired requires concession and is appropriately authorized. Records are maintained in accordance with the QSP 1.2 – Quality Records.

When nonconforming product is detected after delivery or use has started, appropriate actions will be taken to ensure the effects or a potential effect of the nonconformity is resolved and the customer is notified.

8.7.1.1 Customer Authorization for Concession (Not Applicable)

While we only use the scrap disposition, the IMH Group will obtain a customer concession or deviation permission prior to further processing whenever the product or manufacturing process is different from that which is currently approved.

We will obtain customer authorization prior to further processing for "use-as-is" and rework dispositions of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit.

We will maintain a record of the expiration date or quantity authorized under concession in our CATS database. We also ensure compliance with the original or superseding specifications and requirements when

the authorization expires. Material shipped under concession is properly identified on each shipping container (this applies equally to purchased product). The IMH Group will approve any requests from suppliers before submission to the customer.

8.7.1.2 Control of Nonconforming Product- Customer-Specified Process

The organization will comply with applicable customer-specified controls for nonconforming product(s).

8.7.1.3 Control of Suspect Product

Product unidentified or suspect status is classified and controlled as nonconforming product. It will be handled per the QSP 1.21 - Control of Nonconforming Product.

8.7.1.4 Control of Reworked Product (Not Applicable)

While we do not disposition product for rework, the organization would utilize risk analysis (such as FMEA) methodology to assess risks in the rework process prior to a decision to rework the product. If required by the customer, we would obtain approval from the customer prior to commencing rework of the product.

We would define the rework process in accordance with the control plan or other relevant documented information to verify compliance to original specifications. Instructions for disassembly or rework, including re-inspection and traceability requirements, would be accessible to and utilized by the appropriate personnel.

We would retain documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information in our CATS database and NPWO system.

8.7.1.5 Control of Repaired Product (Not Applicable)

Again, we do not disposition product for repair but if we did, the organization would perform a risk analysis (such as FMEA) methodology to assess risks in the repair process prior to a decision to repair the product. We would obtain approval from the customer before commencing repair of the product.

We would define a process for repair confirmation in accordance with the control plan or other relevant documented information in CATS database and NPWO system.

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

We would retain documented information customer authorization for concession for the product to be repaired.

We would also retain documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information in our CATS database.

8.7.1.6 Customer Notification

The IMH Group would immediately notify the customer(s) in the event that nonconforming product has been shipped. Initial communication would be followed with detailed documentation of the event.

8.7.1.7 Nonconforming Product Disposition

The organization controls its scrap through segregation that assures it is not mixed with acceptable product. Product is not disposed of, but recycled, which renders it unusable. Records are maintained. Reference QSP 1.21 - Control of Nonconforming Product for details.

8.7.2
Our QSP 1.21 - Control of Nonconforming Product describes how we identify the nonconformity, define action taken, record any concessions obtained, and identify who has the authority of dispositioning nonconforming product.

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

The IMH Group plans and implements monitoring, analysis, and improvement processes needed to accomplish the following:

a) The determination of what needs to be monitored is primarily performed through our QSP 1.4- Management Review, QSP 1.19 - Internal Audit, and QSP 1.20 - Layered Process Audits. The determination of what needs to be measured is primarily performed through the QSP 1.9 - Design and Development, QSP 1.13 - Production & Service Provision, QSP 1.11 - Purchasing, and QSP 1.4- Management Review which includes our Quality Objectives, metrics and Process Maps.

b) The methods used are documented in the respective procedures or defined by our Quality Objectives, metrics, customer requirements, etc.

c) Monitoring and measuring is performed in part through conformance to our QMS. It is primarily measured and monitored through our QSP 1.4- Management Review and the QSP 1.19 - Internal Audit and QSP 1.13 - Product and Service Provision Procedure.

d) We continuously improve the effectiveness of our QMS when results are analyzed and evaluated through the QSP 1.4- Management Review, QSP 1.19 - Internal Audit, QSP 1.20 - Layered Process Audits, QSP 1.22 - Corrective Action, QSP 1.23 - Preventive Action and Continual Improvement Procedure and Continual Improvement Procedure, and QSP 1.24 - Risk Management as well as other processes.

9.1.1.1 Monitoring and Measurement of Manufacturing Processes

The organization performs process studies on all new production (including assembly or sequencing) processes to verify process capability and to provide additional input for process control, including those for special characteristics. Examples of methodologies used are process capability, measurement systems analysis (MSA), early production containment, in-process verification, etc.

We maintain production process capability or performance results as specified by the customer's part approval process requirements. The organization verifies that the process flow diagram, PFMEA, and control plan are implemented, including adherence to the following:

a) measurement techniques;

b) sampling plans;

c) acceptance criteria;

d) records of actual measurement values and/or test results for variable data and;

e) reaction plans and escalation process when acceptance criteria are not met.

Significant process events, such as tool change or machine repair, is recorded and retained as documented information in our Manufacturing Control System (MCS), Work Order system, and/or FASTMAINT.

We initiate a reaction plan indicated on the control plan and evaluate for impact on compliance to specifications for characteristics that are either not statistically capable or are unstable. These reaction plans include containment of product and 100 percent inspection, as appropriate. A corrective action plan is developed and implemented by the organization indicating specific actions, timing, and assigned responsibilities to ensure that the process becomes stable and statistically capable reference our QSP 1.22 - Corrective Action. The plans are reviewed and approved by the customer, when required.

We maintain records of effective dates of process changes in accordance with our QSP 1.2 - Quality Records.

9.1.1.2 Identification of Statistical Tools

The IMH Group determines the appropriate use of statistical tools. We verify that appropriate statistical tools are included as part of the Advanced Product Quality Planning (APQP, or equivalent) process and included in the design risk analysis (such as DFMEA) (where applicable), the process risk analysis (such as PFMEA), and the control plan.

9.1.1.3 Application of Statistical Concepts

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

9.1.2 Customer Satisfaction

As one of the measurements of performance of the QMS, we monitor information on customer perception as to whether our organization has met customer requirements. We monitor customer satisfaction through the metrics reviewed at the Management Review. Actual metrics reviewed are identified in QSP 1.4-Management Review. The other significant way we receive this information is through e-mail, verbal communications, customer report cards, and other contacts with customers primarily through Sales.

9.1.2.1 Customer Satisfaction

We monitor both internal (i.e. scrap, on-time delivery) as well as external (i.e. customer returns, recalls, customer complaints) customers. In addition, we utilize customer report cards and online portals for this information.

9.1.3 Analysis and Evaluation

We analyze and evaluate appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This includes data by monitoring and measurement, and data from relevant sources.

The results of our analysis are used to evaluate:

a) Conformity of products and services (e.g. PPM, on-time delivery, scrap, etc.).

b) Customer satisfaction (e.g. report cards, customer returns, corrective actions, customer feedback, complaints, etc.).

c) QMS performance (e.g. internal audits, Quality Objectives, Management Reviews, other metrics, etc.).

d) Planning has been implemented effectively (e.g. actions to address risks (see Section 6.1), planning to achieve Quality Objectives (see Section 6.2.2), and planning for changes (see Section 6.3).

e) Actions taken to address risk (see Section 6.1 and above).

f) Performance of suppliers (e.g. supplier quality, supplier delivery, etc.) (see Section 8.4.1 and 8.4.2).

g) Improvement identified throughout our QMS and this manual.

9.1.3.1 Prioritization

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

9.2 Internal Audit

9.2.1
Internal audits of our QMS are an essential part of continuing product and process improvement. They help us ensure that our system conforms to our own requirements for the QMS and the Standard. It also ensures that our QMS is effectively implemented and maintained.

9.2.2
We maintain a process approach to auditing and it is an integral part of monitoring our QMS, identifying and mitigating risk, and continuously improving.

a) Internal audits are planned and scheduled based on the status and importance of the activity. At a minimum, we perform two process audits annually (see Section 4.4.2). However, audits may occur more frequently depending on the results of previous audits, the status and importance of the area, on internal or external requests, or through other system indicators, measurements, and requirements.

   The Management Representative maintains an audit schedule that identifies areas or activities to be audited and when they are scheduled for audit. The schedule considers the importance of the processes, changes that could affect the organization, and results of previous audits.

b) Our QSP 1.19 - Internal Audit as well as the Audit Report will identify the audit criteria and scope for the audits.

c) Our auditor(s) cannot audit their own work and must be objective and impartial to the audit process.

d) The auditor(s) will generate an audit report documenting the audit findings. The Management Representative will enter these findings into CATS database for corrective action (see QSP 1.22 - Corrective Action). The Management Representative maintains records of these audits and corrective actions for the audit findings. The internal auditing process is described in QSP 1.19 - Internal Audit.

e) Management responsible for the area audited ensures that corrections or corrective actions are taken without undue delay to eliminate detected nonconformities and their causes, verification of actions taken, and reporting of verification results.

f) The retained documented information (i.e. records) are maintained in accordance with our QSP 1.2 - Quality Records.

9.2.2.1 Internal Audit Program

Thorough our QSP 1.19 - Internal Audit and QSP 1.20 - Layered Process Audits, we cover the entire QMS including QMS audits, manufacturing process audits, and product audits.

The audit program is prioritized based upon risk, internal and external performance trends, and criticality of the process(es).

If the IMH Group were responsible for software development, we would include software development capability assessments in the internal audit program.

The frequencies of audits are reviewed by the Management Representative and, where appropriate, adjusted based on occurrence of process changes, internal and external nonconformities, and/or customer complaints. The effectiveness of the audit is reviewed as a part of Management Review.

9.2.2.2 Quality Management System Audit

The audit of all QMS processes is covered over each three-year calendar period, according to an annual program, using the process approach to verify compliance with the ISO 9001:2015 QMS Standard, IATF 16949:2016 Automotive QMS Standard. Integrated with these audits, we sample customer-specific QMS requirements for effective implementation. These audits are performed in accordance with QSP 1.19 - Internal Audit.

9.2.2.3 Manufacturing Process Audit

We audit all manufacturing processes over each three-year calendar period to determine their effectiveness and efficiency using customer-specific required approaches for process audits. We determine the approach to be used as identified in our QSP 1.20 - Layered Process Audits.

Within each individual audit plan, each production process is audited on all shifts where it occurs, including the appropriate sampling of the shift handover.

The manufacturing process includes an audit of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents.

9.2.2.4 Product Audit

We perform product audits using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to specified requirements also as part of our QSWI 15.5 - Periodic Inspection.

9.3 Management Review

9.3.1 General

Management holds formal, scheduled reviews of the QMS to ensure its continuing suitability, adequacy, effectiveness, and alignment with our strategic direction. Management reviews are a primary means by which we effect change in our QMS. Management has the responsibility for developing corrective actions and ensuring they are completed. The Management Representative maintains records of the reviews and follow-up activities. The Management Review process is described in QSP 1.4- Management Review.

9.3.1.1 Management Review

Management Reviews are conducted over several meetings that are held minimally annually, but most are held either bi-annually or on a quarterly basis. The frequency of Management Review(s) will be increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the QMS and performance-related issues.

9.3.2 Management Review Inputs

The following inputs are a portion of the Management Review Agenda:

a) the status of actions from previous Management Reviews;

b) changes in external and internal issues that are relevant to the QMS (see also Section 4.2);

c) information on the performance and effectiveness of the QMS, including trends in:

- customer satisfaction and feedback from relevant interested parties;
- the extent to which Quality Objectives have been met;
- process performance and conformity of products and service;
- nonconformities and corrective actions;
- monitoring and measurement results;
- audit results and;
- The performance of external providers (suppliers);

d) the adequacy of resources;

e) the effectiveness of actions taken to address risks and opportunities (see Section 6.1) and;

f) opportunities for improvement;

9.3.2.1 Management Review Inputs Additional

g) cost of poor quality (cost of internal and external nonconformance);

h) measures of process effectiveness;

i) measures of process efficiency;

j) Product conformance;

k) assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1);

l) customer satisfaction (see Section 9.1.2);

m) review of performance against maintenance objectives;

n) warranty performance (where applicable);

o) review of customer scorecards (where applicable);

p) identification of potential field failures identified through risk analysis (such as FMEA) and;

q) actual customer returns and their impact on safety or the environment.

r) yearly summary of design and development monitoring measurements stages (see Section 8.3.4.1)

9.3.3 Management Review Outputs

The output from the Management Review shall include any decisions and actions related to:

a) improvements for the QMS and processes;

b) any need for changes in the QMS;

c) resources needed;

d) action plan to address any performance target/goals not met.

10.0 Improvement

10.1 General

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

We perform this through:

a) Improving products and services to meet requirements as well as to address future needs and expectations.

b) Correcting, preventing or reducing undesired output or effects on our QMS.

c) Improving the performance and effectiveness of the QMS.

Examples of the aforementioned are risk and opportunities, correction, corrective action, continual improvement, and improved profit.

10.2 Nonconformity and Corrective Action

10.2.1
When a nonconformity including complaints or potential nonconformity is determined we perform the following in accordance with our QSP 1.22 - Corrective Action and QSP 1.23 - Preventive Action and Continual Improvement Procedure:

a) Take action to correct it and determine how to address the consequences.

b) We evaluate the cause of the nonconformity or in the case of preventive action for a potential nonconformity (see Section 6.1) and ensure it does not recur or occur elsewhere by reviewing and analyzing the nonconformity, determining the cause, and determining if other potential nonconformities could occur.

c) Implement the action.

d) Review the effectiveness of any corrective or preventive action taken.

e) Update risks and opportunities determined during planning if necessary (see Section 6).

f) Make changes to our QMS.

10.2.2
Our QSP 1.22 - Corrective Action and QSP 1.23 - Preventive Action and Continual Improvement Procedure and Continual Improvement include records to be maintained that identify these nonconformities and subsequent actions taken as well as the result of the corrective and preventive actions in CATS, QCBD, SmarTeam, etc.

10.2.3 Problem Solving

We have a documented process(es) in our QSPs for problem solving including:

a) approaches for various types and scales of problems (e.g., new product development, current production issues, customer returns, audit findings) are defined in in our QSP 1.22 - Corrective Action. We define in the QSP methodologies and define criteria for creating corrective actions in CATS;

b) containment, interim actions, and related activities necessary for control of nonconforming outputs (see Section 8.7);

c) root cause analysis, methodology used, analysis, and results in our 8D process;

d) implementation of systemic corrective actions, including consideration of the impact on similar processes and products in our 8D process;

e) verification of the effectiveness of implemented corrective actions in our 8D process and;

f) reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA, control plan).

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

10.2.4 Error-Proofing

As part of our QSP 1.9 - Design and Development Procedure and QSP 1.13 – Product and Service Provision Procedure, we determine the use of appropriate error-proofing methodologies. Details of the methods used documented in the process risk analysis (e.g. PFMEA, APQP, and test frequencies, etc.) are documented in the control plan.

This process includes the testing of error-proofing devices for failure or simulated failure. Records are in SmarTeam as well as other systems. Error-proofing device failures have a reaction plan.

10.2.5 Warranty Management Systems

We have a return material authorization process in place per our Customer Complaint Cycle (RMA's) Instructions (QSWI 14.4). Included in this process is a method for warranty part analysis, including no trouble found, customer failure, internal nonconformance, etc.

10.2.6 Customer Complaints and Customer Returns Test Analysis

We perform analysis on customer complaints and customer returns as stipulated in Section 10.2.5, and initiate problem solving and corrective action to prevent recurrence.

Where requested by the customer, we will perform an analysis of the interaction of embedded software of our product within the system of the final customer's product. This is currently not applicable.

We would communicate the results of testing/analysis to the customer and within the organization.

10.3 Continual Improvement

We strive to continually improve the suitability, adequacy, and effectiveness of the QMS using the Quality Policy, Quality Objectives, risk analysis, audit results, analysis of data, corrective and preventive actions, Management Reviews, management meetings, and other continuous improvement initiatives.

Our Management Review and other meetings or forums may consider the results of our analysis and evaluation. The outputs from the Management Review and management meetings in the form of actions will determine whether needs and opportunities are addressed as part of continual improvement

10.3.1 Continual improvement

We identify Continuous Improvement Projects (CIPs) through our QSP 1.23 - Preventive Action and Continual Improvement Procedure. It includes our methodologies, objectives, measurement, effectiveness, and documented information. We also assess manufacturing process improvement action plans with emphasis on the reduction of process variation and waste. Last, we assess risk using methods such as FMEA analysis.

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