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Global Quality Manual

The 1st Edition

Musashi Seimitsu Industry Co., Ltd.

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1. Objectives

Following the Musashi Global Policy, Musashi Seimitsu Industry Co., Ltd. (hereinafter referred to as "MSI") and Musashi Group lay down Quality Management System (hereinafter referred to as "QMS") in Global Quality Manual (hereinafter referred to as "GQM") aiming to provide products that satisfy normative requirements and customer-specified requirements and to aim continual system improvement that focus on customer satisfaction, reduction of defect prevention and variation.

2. Scope

This GQM is applied to production of our products and sales activity. IATF 16949 is applied to the quality management system over product design, manufacturing process design, production and shipment of automobile steering and suspension ball joints, and the process over manufacturing process design, production and shipment of motorcycle parts, transmission gears and camshafts.

3. Operational method

3.1 Global Quality Manual Establishment and Revision

The GQM shall be established / revised by Quality Assurance Div. of MSI and issued with the approval of MSI head of Quality Assurance Division (Quality responsible). The GQM shall be revised as necessary and the revised area shall be specified with underline. The revised section and the reason shall be recorded in revision record field.

Due to reorganization, if only organization names are changed without changing work contents, the organization names written on the standards shall be replaced with new ones as a provisional measure.

Any inquiries concerning GQM text is asked to Quality Assurance Div. of MSI.

3.2 Distribution

The GQM is distributed to sites by Quality Assurance Div. of MSI and each site shall control it that can be referred the latest version by all employees of all departments as necessary.

3.3 Original retention

Quality Div. of MSI shall store the original and the old edition needs to be distinguished in principle. In case the original needs to be stored, it shall be identified.

3.4 Terms and definitions

The GQM is defined with the terms and definitions given in ISO9000 (JIS Q 9000) and IATF16949.

3.4.4 "Important Characteristics" or "Important topics"

Same meaning with "Specified characteristics" in IATF16949

3.4.6 "Control Plan"

It means a document on the system and the process that is required to control products.

3.4.7 "Manager of department"

It means managers of division, room, department, group and management leaders of each department.

3.5 Normative reference

IATF16949, JIS Q9001 (ISO 9001), JIS Q 9000 (ISO 9000), official explanations and manuals for FMEA, MSA, SPC, APQP, PPAP

4 Context of the organization

4.1 Understanding the organization and its context

We determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. We monitor and review the information.

4.2 Understanding the needs and expectations of interested parties

We determine the interested parties and the requirements that are relevant to the QMS, to effect providing products that meet customer and applicable statutory and regulatory requirements. We also monitor and review the information.

4.3 Determining the scope of the quality management

We show scope of QMS in "Organization Chart".

4.3.1 Determining the scope of the quality - supplemental

Remote support department is included scope of QMS.

4.3.2 Customer-specific requirements

Customer-specific requirements is confirmed the contents and express requirements that decide how to apply to QMS of each site.

4.4 Quality management system and its processes

4.4.1 Due to establish, implement, maintain and continually improve QMS, including the processes needed and their interactions, in accordance with the IATF16949 requirements, we shall:
The process needed to QMS is applied throughout each site.

a) determine the inputs required and the outputs expected from these processes "Flowcharts or turtle diagrams";
b) determine the sequence and interaction of these processes in "Quality Assurance System Chart"
c) determine the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes in "Quality System Documentation" ;
d) determine the resources needed for these processes and ensure their availability;
e) assign the responsibilities and authorities for these processes;
f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
g) evaluate these processes and implement any changes needed to ensure that these processes achieve their objective;
h) improve the processes and QMS.

4.4.1.1 Conformance of products and processes

We ensure conformance of all products and processes, including service parts and those that are outsourced to all applicable customer, statutory, and regulatory requirements (see Section 8.4.2.2).

4.4.1.2 Product safety

We determine each department: regulations, including following items, for the management of products and manufacturing processes related product-safety.

a) identification of statutory and regulatory requirements;
b) customer notification related to item a);
c) special approvals for design FMEA;
d) identification of product safety-related characteristics
e) identification and controls of safety-related characteristics of product and manufacturing process;
f) special approval of control plan and process FMEAs;

g) reaction plans (see Section 9.1.1.1)

h) defined responsibilities, definition of escalation process and flow of information, including CEO and responsible person for Quality Assurance, and customer notification;

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

j) We approve changes of product or process prior to implementation, including evaluation of potential effects on product safety from process and product changes (see ISO9001, Section 8.3.6);

k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (see Section 8.5.2.1);

1) 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.

NOTE: Special approval is an additional approval by the function (typically the customer) that is responsible to approve such documents with safety-related content.

4.4.2 In QMS and the process, we shall;

a) maintain and control regulated document of the operation of its processes;

b) storage documented records to be evidences that processes are being carried out as planned.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

Quality responsible person of each site shall demonstrate leadership and commitment with respect to the QMS by:

a) taking accountability for the effectiveness of the QMS;

b) ensuring that the quality policy and quality objectives are established and chain of business planning;

c) ensuring the establishment of QMS that is correspondence with our business processes;

d) promoting the use of the process approach and risk-based thinking;

e) introducing each department's leader to propose resources (employees, facility, equipment, and money) needed to QMS;

f) notifying the importance of confirming to the QMS to all employees;

g) ensuring that the QMS achieves its intended results;

h) setting opportunities employees to contribute to the effective operation of QMS;

i) promoting improvement;

j) assigning managers of department on roles to demonstrate their leadership in each department.

5.1.1.1 Corporate responsibility

We obey actions in accordance with “Our compliance” (including at a minimum an anti-bribery policy, an employee code of conduct, and an ethics escalation policy (“whistle-blowing policy”)).

5.1.1.2 Process effectiveness and efficiency

Quality responsible person of each site implement management review to evaluate and improve effectiveness and efficiency of the product realization processes and support processes.

5.1.1.3 Process owners

Quality responsible person of each site assigns process owner (responsible person) to the processes. Process owners understand their roles and competent to perform those roles (see Section 7.2).

5.1.2 Customer focus

We determine customer and applicable statutory and regulatory requirements and instruct to each managers to satisfy the requirements:

a) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
c) the focus on enhancing customer satisfaction

5.2 Policy

5.2.1 The quality policy of the Musashi Group is based on the global policy "MGP - 04 - 001".

Group CEO of MSI shall establish and maintain a quality policy that:

a) is appropriate to our purpose and context of the organization and guides direction of business planning;
b) provides a framework for setting quality objectives;
c) promises to satisfy applicable requirements;
d) ensures to continual improvement of the QMS.

5.2.2 Communicating the quality policy

The quality policy shall be communicated to;

a) be available and be maintained as documented information;
b) posted on website of MSI;
c) be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

CEO of MSI assigns the quality responsible person to of MSI head of Quality Assurance Div.

In each site, CEO of each site assigns the quality responsible person. However, it can not work concurrently with the person responsible for the manufacturing department.

In each site, clarify the roles and responsibilities and authorities of each department.

Quality responsible person of each site assigns the responsibility and authority for:

a) ensuring that the QMS conforms to the requirements of IATF16949;
b) ensuring that the processes are delivering their intended outputs;
c) reporting on the performance of the QMS and on opportunities for improvement (see 10.1) to CEO;
d) ensuring the promotion of customer focus throughout in-house;
e) instructing responsible person for quality assurance to conform considering the affection to GQM when changes the QMS are planned by the results of internal or external audit and management review.

5.3.1 Organizational roles, responsibilities, and authorities - supplemental

Quality responsible person of each site assigns personnel with the responsibility and authority for process control, implementation, and verification activity to satisfy customer requirements.

Ex:

The selection of important characteristics, Setting quality objectives and related training, Corrective and preventive actions, Product design and development, Production capacity analysis, Logistics information, Customer scorecards, Customer portals

5.3.2 Responsibility and authority for product requirements and corrective actions

Quality responsible person of each site ensure that:

a) Quality responsible person of manufacturing department have the authority to stop production and start production to correct quality problems. In case the problem might affect to quality of shipping products, responsible of manufacturing department have the authority to stop shipment.
b) employees inform the information to quality chief administrator of quality responsible person of manufacturing to prevent occurrence of quality defect of shipped products and lot defect.
c) responsible of manufacturing department have staff personnel in charge of manufacturing quality of production operations across all shifts.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for establishment and management of QMS, we consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that needs to be addressed to:

a) ensure that the QMS achieve its intended result(s);
b) utilize effects that bring desirable situation for a)
c) prevent, or reduce effects that bring undesired situation for a)
d) improve occurred matters.

6.1.2 We plan;

a) actions to address these risks and opportunities defined by Section 6.1.1
b) how to:
   1) integrate and implement the actions into our QMS (see 4.4).
   2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of product requirements.

6.1.2.1 Risk analysis

We implement risk analysis utilizing such as FMEA method and maintain the result.

Risk analysis reflects at a minimum;

lessons learned from product recalls, product audits, field returns, repairs, complaints, scrap and rework.

6.1.2.2 Preventive action

We determine and implement action(s) to eliminate the causes of potential defects in accordance with affection of defects to prevent their occurrence:

a) determining potential defects and their causes;
b) evaluating the need for action to prevent occurrence of defects;
c) determining and implementing action needed;
d) records of result of action taken (see 4.2.4) ;
e) reviewing the effectiveness of the action taken in a)~d);
f) applying to other similar processes.

6.1.2.3 Contingency plans

We shall;

a) identify and evaluate internal and external risks to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that

customer requirements are met;

b) define contingency plans in accordance with risk and impact to the customer;

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

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

e) periodically test the contingency plans for effectiveness;

f) conduct contingency plan review (at a minimum annually) using a multidisciplinary team including administrators, and update as required;

g) document the contingency plans and retain records of the history and the person who approved if changed.

The contingency plans include provisions to validate that the manufactured product continues to meet customer specifications as following cases;

・in case re-started production after an emergency in which production was stopped;

・in case the regular shut-down processes were not followed.

6.2 Quality objectives and planning achieve them

6.2.1 We establish quality objectives at each department, levels and processes needed for the QMS and control them including business plans.

The quality objectives satisfy to;

a) be consistent with the quality policy;

b) be measurable;

c) take into account applicable requirements;

d) be relevant to conformity of products and services and to enhancement of customer satisfaction;

e) be monitored;

f) be communicated;

g) be updated as appropriate.

6.2.2 When planning how to achieve its quality objectives, we shall determine;

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

6.2.2.1 Quality objectives and planning to achieve them - supplemental

Quality responsible person of each site instructs general managers of departments to consider meeting customer requirements for quality objectives. The results of the review regarding interested parties and their relevant requirements are considered when we establish a next year's quality objectives and related performance targets (internal and external).

6.3 Planning of changes

When we determine the need for changes to the QMS, the changes are carried out in a planned manner considering:

a) the purpose of the changes and their potential consequences
b) the integrity of the QMS;
c) the availability of resources;
d) the allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

We determine the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS. We shall consider;

a) the capabilities of, and constraints on, existing internal resources;
b) what needs to be obtained from external providers.

7.1.2 People

We assign the employees necessary for the effective implementation of the QMS and for the operation and control of its processes.

7.1.3 Infrastructure

We determine and provide the infrastructure necessary for conformity achievement of product requirements and for the operation of its processes to each department. We maintain them to work correctly.

NOTE Infrastructure can include:

a) buildings and associated utilities (electrics, air etc.);
b) equipment (including hardware and software);
c) transportation resources;
d) information system.

7.1.3.1 Plant, facility, and equipment planning

A multidisciplinary team develops and improves plant, facility, and equipment plans in accordance with manufacturing control plan considering risk identification and risk mitigation.

In designing plant layouts, we shall:

a) optimize material flow, material handling, and effective utilization of floor space, including control of nonconforming product, and
b) facilitate synchronous material flow, as applicable.

We develop and implement methods to evaluate manufacturing feasibility for new product or new operations. Manufacturing feasibility assessments include production capacity planning. These methods are applied to evaluate proposed changes to existing operations.

We maintain process effectiveness by incorporating any changes made during process approval, control plan maintenance (see Section8.5.1.1), and verification of job set-ups (see Section8.5.1.3), including periodic re-evaluation relative to risk.

Assessments of manufacturing feasibility and evaluation of capacity planning are inputs to management reviews (see ISO 9001, Section 9.3)

7.1.4 Environment for the operation of processes

We determine, provide and maintain the working environment necessary to achieve the operation of its processes and conformity of products.

NOTE A suitable environment is a combination of human and physical factors, such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);
b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective)
c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise)

7.1.4.1 Environment for the operation of processes - supplemental

We maintain its premises in a state of order, cleanliness and repair that its consistent the product and manufacturing process needs.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

We define monitoring and measurement to “Work Standard” to verify the conformity of products to requirements. We define documented management and calibration procedure (including following items) for monitoring equipment (process parameter monitoring machine) and measurement equipment (machine to verify product conformity, hereinafter measurement equipment including monitoring machine) descripted in “Work standard”, and instruct how to control and treat to maintain them for manufacturing department.

We shall ensure that the measuring equipment provided:

a) are suitable for the specific type of monitoring and measurement activities being

undertaken;

b) are maintained to ensure their continuing fitness for their purpose.

7.1.5.1.1 Measurement system analysis

We implement statistical studies utilizing MSA study guide to analyze variation present in the results of each type of measuring equipment identified in the control plan. The studies priority focuses on importance or important item of products and processes. We obey it when it has a customer specified analysis method.

When we use substitutional analysis method, we retain records of customer approval.

7.1.5.2 Measurement traceability

Due to verify measurement traceability, measurement equipment is:

a) calibrated or verified at specified intervals, or prior to use, against standards traceable to international or national measurement standards; when no such standards exist, the used basis shall be recorded.
b) identified the calibration states;
c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

We evaluates the validity of previous measurement results when measuring equipment is found to be non-conformity, and takes appropriate action as necessary.

7.1.5.2.1 Calibration / verification records

We have a documented process for managing calibration /verification records. Periodic records of the calibration /verification activity for all measuring equipment (including employee-owned equipment relevant for measuring, customer-owned equipment, or in-plant supplier-owned equipment) needed to provide evidence of conformity to internal requirements, legislative and regulatory requirements, and customer-defined requirements are maintained including:

a) revisions following engineering changes (dimension changes) that impact measurement systems;

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

c) an assessment of the risk of the product requirements caused by the out-of-calibration specification;

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

e) notification to the customer if suspect product or material has been shipped;
f) description of specification acceptance after periodic calibration;
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 gauging (including employee-owned equipment, customer-owned equipment, or in-plant 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 in-plant supplier –owned equipment).

7.1.5.3 Laboratory requirements

7.1.5.3.1 Internal laboratory

We define scope of laboratory and include followings about inspection, test, or calibration to QMS and implement them.

a) We define and maintain procedure for acceptance, identification, handling, protection, retention and scrap of measurement instruments that shall be inspected, tested and calibrated;
b) Assignment of the laboratory personnel that have competency of inspection, test and calibration;
c) Utilize appropriate test or periodic check method that proper to accepted inspection, test and calibration and that meet customers' needs including sampling method.

We confirm in advance to be able to implement inspection, test and calibration in accordance with specification. We solve the problem talking with customer in case that we cannot implement in accordance with specification or should implement with another method.

d) Capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.); when no national or international standard(s) is available, we define and implement a methodology to verify measurement system capability;
e) Customer requirements, if any;
f) Review of above activity records.

7.1.5.3.2 External laboratory

External laboratory facilities used for inspection, test, or calibration services shall we 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 include the mark of a national accreditation body; or

— 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.

7.1.6 Organizational knowledge

We determine and maintain the knowledge necessary for the operation of its processes or to achieve conformity of products and services, and this knowledge is made available to the extent necessary. When addressing changing needs and trends, we consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

We implement followings regarding employee competence.

a) determine the necessary competence of person(s) doing work that affects the conformity of product requirements with a skill map.
b) implement appropriate education, evaluate the effectiveness and ensure that employees are competent;
c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
d) maintain records of education, training, skill and experience.

7.2.1 Competence – supplemental

We establish and maintain a documented process (es) for identifying training needs including awareness (see Section 7.3.1) and achieving competence of all personnel performing activities affecting conformity to product requirements. Personnel performing specific assigned tasks is qualified, if necessary, to satisfy customer requirements.

7.2.2 Competence – on-the-job training (OJT)

We implement on-the-job training for all personnel in any new or modified affecting conformity to product requirements, internal requirements, regulatory or legislative requirements; this includes

- education training of customer requirements
- contract or agency personnel
- require proper level in accordance with complexity of necessary task to implement daily work of each operator

・include in the training to instruct that defects for quality requirements affects to customer

7.2.3 Internal auditor competency

We have a documented process (es) to qualify competent internal auditors, taking into account any customer-specific requirements. (For guidance on auditor competencies, refer to ISO 19011.) We maintain a list of qualified internal auditors.

QMS auditors, manufacturing process auditors, and product auditors are able to 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 (such as PFMEA) and control plan. Product auditors demonstrate competence regarding understanding product requirements and use of relevant measuring and test equipment to verify product conformity.

Where training is implemented to achieve competency, documented information is retained to demonstrate the trainer's competency with the above requirements.

Maintenance and improvement of internal auditor competence is demonstrated through:

f) executing a minimum number of audits per year, as we defined; 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 understanding and competencies of the following in a minimum;

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

b) applicable customer and our 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 PFMEA and control plan;

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.

7.3 Awareness

We ensure that employees are aware of:

a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the QMS, including the benefits of improved performance;
d) the implications of not conforming with the QMS requirements.

7.3.1 Awareness - supplemental

We maintain documented information that demonstrates that all employees are aware of the importance of following activity;

・their impact on product quality including customer requirements and the risks involved for the customer with non-conforming product;

・achieving, maintaining, and improving quality objectives.

7.3.2 Employee motivation and empowerment

We maintain a documented process(es) to motivate employees to achieve quality objectives, to make continual improvements to create an environment that enhance quality awareness through quality enlightenment and improvement proposal.

7.4 Communication

We implement the internal and external communications relevant to the QMS determining;

a) on what it will communicate;
b) when to communicate;
c) participants;
d) how to communicate;
e) who charges in.

7.5 Documented information

7.5.1 General

QMS of each site includes:

a) documentation or records required by GQM;

b) documentation or records determined to be necessary for the effectiveness of the QMS.

7.5.1.1 Global Quality management system documentation

GQM clarifies the following.

a) QMS application scope (4.3)

b) documented process (4.4.1)

c) process order and correlation (4.4.1)

d) where is taking action of customer requirements in QMS

7.5.2 Creating and updating

When creating and revising documentation, we ensure appropriate:

a) identification (a title, date, author, or document number);
b) format (language, software version, graphics) and media (paper, electronic);
c) review and approval.

7.5.3 Control of documented information

7.5.3.1 Management of documentation and records required by GQM is observed that;

a) it is available for use , where and when it is needed;
b) it is adequately protected (from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documentation, we ensure the implementation of the following activities:

a) distribution, access authority, retrieval and use;
b) storage and preservation for preservation of legibility;
c) control of changes (version control, revision history);
d) retention and disposition.

We control and communicate to related division to identify outsourced documentation which we determine as necessary documentation. We control and communicate to related division to identify outsourced documentation which we determine as necessary documentation.

Documentation and records are protected from unintended alterations.

7.5.3.2.1 Record retention

We control records based on “Quality record retention procedure”. For control of records, we obey statutory, regulatory, organization, and customer requirements.

Production part approvals, tooling records (including maintenance and ownership), product and process design records, purchase orders (if applicable), or contracts and amendments shall be 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.

7.5.3.2.2 Engineering specifications

We define into documentation a content confirmation, distribution to related department, and application to in-house regulation for all customer engineering standards/specifications and the changes based on customer schedules, as required.

When an engineering standard/specification change results in a product design change, refer to Section 8.3.6. When an engineering standard/specification change results in a product realization process change, refer to Section 8.5.6.1. Related departments review documentations ("Drawing", "FMEA", "Work Standard", "Control Plan" etc.), as appropriate, based on its changes and control updated documents. We retain a record of the date on which each change is implemented in production.

Check of context should be completed within 10 working days of receipt of notification of engineering standards/specifications changes.

8 Operation

8.1 Operational planning and control

We define manufacturing control plan including followings to meet the requirements for the provision of products and to implement the actions for risk and opportunities:

a) determining the requirements for the products;
b) establishing criteria for:
   1) the processes;
   2) the acceptance of products;
c) determining the resources needed;
d) control method of the processes in accordance with the criteria b);
e) determining, maintaining and retaining records necessary;
   1) to have confidence that the processes have been carried out as planned;
   2) to demonstrate the conformity to product requirements.

We control planned changes and review the consequences of unintended changes, taking corrective or preventive action for reoccurrence.

We ensure that outsourced processes are controlled.

8.1.1 Operational planning and control - supplemental

The following topics are included in product control planning:

a) customer product requirements and technical specifications;
b) logistics requirements;
c) manufacturing feasibility;
d) project planning (refer to ISO 9001, Section 8.3.2);
e) acceptance criteria.

The resources identified in Section 8.1 c), it's for the required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for product acceptance.

8.1.2 Confidentiality

We ensure the confidentiality of customer-contracted products under development and related product information.

8.2 Requirements for products and services

8.2.1 Customer communication

We assign person in charge and communicate with customer about following topics by documentation, telephone and e-mail.

a) Providing information relating to products;
b) Handling enquiries, contracts or orders (including changes);
c) Obtaining customer feedback relating to products including customer complaints;
d) Handling or controlling customer property;
e) Specific requirements for contingency actions.

8.2.1.1 Customer communication – supplemental

We communicate in the language agreed with the customer using customer-specified language and format (e.g., computer-aided design data, electronic data interchange).

8.2.2 Determining the requirements for products and services - supplemental

We consider the followings and define product requirements.

a) the requirements for the products and services are defined, including
   1) any applicable statutory and regulatory requirements;
   2) those considered we need;
b) we can meet the claims for the products it offers.

8.2.2.1 Determining the requirements for products and services - supplemental

These requirements shall include specified characteristics by the result of organization knowledge about recycle, environmental effect, products and manufacturing process.

Compliance to ISO 9001, Section 8.2.2 item a) 1), include: all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

8.2.3 Review of the requirements for products and services - supplemental

8.2.3.1

We ensure that it has the ability to meet the requirements for products to be offered to customers. We review requirements for products. This review is implemented before submission of estimates, before acceptance of contracts or orders, before change of contracts or orders. The review is confirmed the following:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
c) requirements we specified;
d) statutory and regulatory requirements applicable to the products and services;
e) contract or order requirements differing from those previously expressed.

We resolve that before contract or order acceptance in case it differs from those previously expressed.

We confirm customer's requirements before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.1.1 Review of the requirements for products and services - supplemental

When it does not implement official review required by Section 8.2.3.1, we retain evidence of customer's approval.

8.2.3.1.2 Customer-designated special characteristics

Control customer-specified important characteristics including to followings;

「Drawing」,「D-FMEA」,「P-FMEA」,「Work Standard」

「Inspection Standard」,「Control Plan」,「Quality Data Records」

8.2.3.1.3 Organization manufacturing feasibility

We 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 customer. This feasibility analysis is conducted for any new manufacturing or product technology for any changed manufacturing process or product design.

8.2.3.2 We retain documented information:

a) on the results of the review;

b) on any new requirements for the products.

8.2.4 Changes to requirements for products and services

When changing product requirements, we review related documentation based on defined procedure and notify to related department.

8.3 Design and development of products and services

8.3.1 General

We define and control planning of product design and development.

8.3.1.1 Design and development of products and services - supplemental

The requirements of Section 8.3.1 apply to product and manufacturing process design and development and focus on error prevention rather than detection.

We document the design and development process in 「Design Control Regulation」

8.3.2 Design and development planning

We determine the stages and controls for design and development considering:

a) the nature, duration and complexity of the design and development activities;
b) the required process stages (including applicable design and development reviews);
c) the required design and development verification and validation;
d) the responsibilities and authorities involved in the design and development process;
e) the internal and external resource needs for the design and development of products and services;
f) the need to control interfaces between persons involved in the design and development process;
g) the need for involvement of customers and users in the design and development process;
h) the requirements for design and development subsequent provision of products and services;
i) the level of control expected for the design and development process by customers and other relevant interested parties;
j) the records needed to demonstrate that design and development requirements have been met.

8.3.2.1 Design and development planning - supplemental

We organize a multidisciplinary team that includes affected stakeholders to design and development planning within the organization and, as appropriate, its supply chain. We implement followings:

a) project management (for example, APQP or VDA-RGA);
b) project and manufacturing process design activities (for example, DFM and DFA), such as consideration of the use of alternative designs and manufacturing processes;

c) development and review of D-FMEA, including actions to reduce potential risks;
d) development and review of manufacturing process risk analysis (for example, P-FMEA, process flows, control plans, and work standards).

8.3.2.2 Product design skills

Our engineering defines needed or proper tool and skill for product design. They qualify personnel who can realize design requirements and assign to design/development work.

8.3.2.3 Development of products with embedded software

Not applicable currently.

8.3.3 Design and development inputs

We determine inputs related to design and development considering;

a) functional and performance requirements;
b) information derived from previous similar design and development activities;
c) statutory and regulatory requirements;
d) standards or codes of practice that we have committed to implement;
e) potential consequences of failure due to the nature of the products.

Inputs are adequate for design and development purposes, complete and to exclude ambiguous. Conflicting inputs are resolved.

We retain records on inputs.

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:

a) product specifications including important item;
b) boundary and interface requirements;
c) identification, traceability, and packing;
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, conservation, hygiene, safety, environmental, development timing, and cost;
g) applicable statutory and regulatory requirements of the customer-identified country of destination (if provided);
h) embedded software requirements (We are not applicable).

We have a process to gain information of previous design projects, competitive product

analysis (benchmarking), supplier feedback, internal input, field data, and other relevant information for similar projects.

8.3.3.2 Manufacturing process design input

We determine, document, and review manufacturing process design input requirements including followings:

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 and design for assembly
i) previous quality information

The manufacturing process design includes the use of error-proofing methods to a degree commensurate with the risks encountered.

8.3.3.3 Important characteristics

We use a multidisciplinary approach to establish, document, and implement its process (es) to perform important items determined by risk analysis, and it includes the following:

a) control including customer important markings and our specified important markings in the drawings (as required), risk analysis (such as FMEA), control plans, work standards, inspection standards, quality data records, and start-up check sheets;
b) approval of control and monitoring method for important items of products and manufacturing processes;
c) customer approvals (when required);
d) compliance with in-house equivalent symbols or notations, as defined in a symbol conversion table, definitions and symbols required by customer requirements;

8.3.4 Design and development controls

We apply controls to the design and development process to ensure that:

a) the targets of design are defined;
b) reviews are conducted to evaluate whether if the results of design and development meets requirements or not;

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;
d) validation activities are conducted to ensure that the resulting products meet the defined requirements and needs for users,
e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
f) the result of these activities is retained.

8.3.4.1 Monitoring

We input the design audit result of product design and manufacturing process design to management review.

8.3.4.2 Design and development validation

We conduct design and development validation in accordance with customer requirements and customer specified timing including any applicable industry and governmental agency-issued regulatory standards.

Where contractually agreed with the customer, this includes evaluation of the interaction of our product, including embedded software, within the system of the final customer's product.

8.3.4.3 Prototype programme

We control prototype based on procedures. When required by customer, we make a prototype control plan. We use, whenever possible, the same suppliers, tooling, and manufacturing process as will be used in production. We complete all performance-testing activities and monitor conformity to requirements. When services are outsourced, we include the type and extent of control in the scope of QMS. (see Section 8.4).

8.3.4.4 Product approval process

We establish, implement, and maintain processes to be approved product (initial product card) and process (control plan) based on procedures defined by the customer(s).

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

We obtain documented product approval prior to shipment, if required by the customer, and retain the records of such approval.

8.3.5 Design and development outputs

We ensure that the design and development outputs are the followings and retain the

records;

a) meet the input requirements;
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;
d) specify the characteristics of the products that are essential for their intended purpose and their safe and proper provision.

8.3.5.1 Design and development outputs – supplemental

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

a) design risk analysis (FMEA);
b) reliability study results;
c) product important item;
d) results of product design error-proofing, such as DFSS, DFMA, and FTA;
e) product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning& tolerancing (GD&T);
f) 2D drawings, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);
g) product design review results;
h) service diagnostic guidelines and repair and serviceability instructions;
i) service part requirements;
j) packing and labeling requirements for shipping.

8.3.5.2 Manufacturing process design output

We document the manufacturing process design output in a manner that enable verification against the manufacturing process design inputs. The manufacturing process design includes the followings:

a) specifications and drawings;
b) important item for product and manufacturing process;
c) identification of process input variables that impact characteristics;
d) tooling and equipment for production and control, including capability studies of equipment and process(es);
e) manufacturing process flow charts/layout, including linkage of product, process, and tooling;
f) capacity analysis;
g) P-FMEA;
h) maintenance plans and instructions;
i) control plan;
j) work instructions and work standard;
k) process approval acceptance criteria
l) data for quality, reliability, maintainability, and measurability;
m) results of error-proofing identification and verification, as appropriate;
n) methods of rapid detection, feedback, and correction of product/manufacturing process

nonconformities.

8.3.6 Design and development changes

We document and review changes made during, or subsequent to, the design and development of products that impact on conformity to requirements. We retain records including:

a) design and development changes;
b) the result of reviews;
c) the authorization of the changes;
d) the actions taken to prevent adverse impacts.

8.3.6.1 Design and development changes – supplemental

We evaluate all design changes after initial product approval for potential impact on fit, form, function, performance, and/or durability (including changes proposed by supplier).

The changes is validated against customer requirements and approved in-house, prior to mass production start. If required by the customer, we obtain documented approval, or a documented waiver, from the customer prior to mass production start.

For products with embedded software, we document the revision level of software and hardware part of the change record. (We are not applicable currently)

8.4 Control of externally provided processes, products and services

8.4.1 General

We ensure that purchasing and outsourced products conform requirements. We determine applied control method and control;

a) purchasing products and outsourced products are intended into our products;
b) products are provided directly to customer from supplier;
c) process, or part of a process, is provided by supplier.

We conduct evaluation, selection, monitoring of performance, and re-evaluation based on their

8.4.1.1 General – supplemental

The application scope of Section 8.4 include all products that affect customer requirements such as sub-assembly, sequencing, sorting, rework, and calibration services

8.4.1.2 Supplier selection process

We have a documented supplier selection process including the followings:

a) an assessment of the risk to product conformity and uninterrupted supply to customer;
b) relevant quality and delivery performance;
c) an evaluation of QMS;
d) multidisciplinary decision marking; and
e) an assessment of software development capabilities. (We are not applicable currently)

It 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.

8.4.1.3 Customer-directed sources (also known as "Directed-Buy")

We materials from approved supplier when it is specified by contract. All requirements of Section 8.4 (except the requirements Section 8.4.1.2) are applicable to the supplier control of customer-directed sources unless specific agreements are otherwise defined by the contract between the customer and us.

8.4.2 Type and extent of control

We ensure that provided processes and products do not adversely affect our ability to consistently deliver conforming products with customer requirements.

We shall:

a) ensure that supplier's processes remain within the control of our QMS;
b) define both the controls that it intends to apply to supplier and those it intends to apply to the resulting output;
c) take into consideration:
    1) the potential impact of the supplier's processes and products on the organization's ability to meet customer and applicable statutory and regulatory requirements;
    2) the effectiveness of the controls applied by supplier;
d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.2.1 Type and extent of control – supplemental

We have a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products and processes to

our and customer requirements.

The process includes the criteria and action contents of control method changes and quality measures based on supplier performance, assessment of product and material risks.

8.4.2.2 Statutory and regulatory requirements

We document their process to ensure that purchased products and processes conform to the current applicable statutory and regulatory requirements in the country of receipt, the country of shipment, and the customer-identified country of destination, if provided.

If the customer defines special controls for certain products (including at suppliers) with statutory and regulatory requirements, we obey and maintain that.

8.4.2.3 Supplier quality management system development

We require our suppliers to develop, implement, and improve a QMS certified to ISO 9001 (except for authorized by the customer [e.g. item a] below) with the ultimate objective that supplier acquire IATF 16949 certification.

The following sequence should be achieving this requirement (unless otherwise specified by the customer):

a) compliance to ISO 9001 (we implement audit);
b) certification of ISO 9001 (certificated by third-party certification);
c) certification of ISO 9001 (certificated by third-party certification) + compliance to other customer-defined QMS requirements;
d) certification of ISO 9001 (certificated by third-party certification) + compliance to IATF 16949 (we implement audit);
e) certification of IATF 16949 (certificated by IATF-recognized certification body).

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

We are not applicable currently.

8.4.2.4 Supplier monitoring

We have a documented process and criteria to evaluate supplier performance in order to ensure conformity of externally provided products and processes to our and customer requirements. Each department, at a minimum, monitors the following performance indicators:

a) delivered product conformity to requirements;
b) customer shutdown (including yard holds and stop ships), Production Control department;
c) delivery schedule performance;
d) number of occurrences of premium freight;

If provided by the customer, we also include the following:

e) special status customer notifications (related to quality or delivery issues);
f) dealer returns, warranty, field actions, and recalls.

8.4.2.4.1 Second-party audits

We implements audit to conduct the following for supplier and retain the records.

a) risk assessment;
b) monitoring;
c) QMS development;
d) product audits;
e) process audits.

We document the criteria for determining the need, type, frequency, and scope of audits. The criteria are based on the following risk analysis. (Product safety/regulatory requirements, performance of the supplier, and QMS certification level)

If audits supplier's QMS, the approach is consistent with the automotive process approach.

8.4.2.5 Supplier development

We determine the priority, type, extent, and timing considering the following and try to improve quality level of its active suppliers.

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) QMS certification status;
d) risk analysis.

We implement actions necessary to resolve open (unsatisfactory) performance issues and pursue opportunities for continual improvement.

8.4.3 Information for external providers

We confirm the adequacy of requirements prior to order to supplier. Requirements of their communication include the following:

a) the processes and products to be provided;
b) the approval of:
    1) products
    2) methods, processes and equipment;
    3) the release of products
c) required competence (including required qualification)
d) supplier's interactions with us
e) control and monitoring of supplier's performance to be applied by us
f) verification or validation activities that we, or its customer, intends to perform at supplier.

8.4.3.1 Information for external providers – supplemental

We communicate all applicable statutory and regulatory requirements and important item of products and processes to supplier, and require the suppliers to cascade all using sheets/charts down chain to the point of manufacture.

8.5 Production

8.5.1 Control of production

We implement production process under controlled conditions. Controlled conditions include, as applicable:

a) make and manage documented information that defines:
   1) the quality characteristics of the products, work contents and method;
   2) the quality indicators
b) the availability and use of monitoring machine and measuring equipment;
c) monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products have been met;
d) suitable infrastructure and environment for the operation of processes;
e) competent persons (including any required qualification);
f) Specific processes that appear process failure only at step of product use are plating, welding and heat treatment process in our company. We conduct validation check by evaluation before mass production launch up and each event evaluation by customer;
g) the implementation of actions to prevent human error;
h) the implementation of delivery and post-delivery activities.

8.5.1.1 Control Plan

Multidisciplinary team develops control plans (in accordance with annex A) at the system, subsystem, component, and/or material level for all products. For similar parts using a common manufacturing process, the use of common control plan is applicable. We make a control plan of mass production prototype stage and mass production stage considering the result of D/P-FMEA.

If required by the customer, provide measurement and conformity data collected at making control plans.

a) manufacturing process control (including verification of job set-ups);
b) first-off/last-off part validation (as applicable);
c) methods for monitoring of important item defined by customer and us;
d) the customer-required information (if any);
e) specified reaction plan when nonconforming product is detected, the process becomes statistically unstable or not statistically capable.

We review control plans, and revise as required, for any of the following:

f) when shipped nonconforming product to the customer;
g) when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA);
h) after implementation of corrective action for customer complaint (as applicable);
i) at a set frequency based on a risk analysis.

If required by the customer, we obtain customer approval after review or revision of the control plan.

8.5.1.2 Standardised work – operator instructions and visual standards

We make a work standard, work procedure and appearance standards satisfied with:

a) communicated to and understood by the employees who are responsible for performing the work;
b) legible;
c) descripted in the language(s) understood by the operator responsible to follow them;
d) accessible for use at the designated work area(s).

Work procedure includes rules for operator safety.

8.5.1.3 Verification of job set-ups

We implement the following for changeover:

a) verify job set-ups when performed, such as an initial run of job, material changeover, or job change that required a new set-up;
b) prepare work procedure and work standard for set-up personnel;
c) use statistical methods of verification (where applicable);
d) perform first-off/last-off part validation (as applicable)
where appropriate, first-off parts should be retained for comparison with the last-off parts and last-off parts are retained till subsequent runs;
e) retain records of process and product approval following set-up and first-off/last-off part validations.

8.5.1.4 Verification after shutdown

We define and implement processes to confirm conformity to product requirements after manufacturing stop,

8.5.1.5 Total productive maintenance

We document, implement and maintain TPM system including the following:

a) identification of process equipment necessary to procedure conforming product at the required volume;
b) availability of replacement parts for the equipment identified in item a);
c) provision of resource for machine, equipment, and facility maintenance;
d) packaging and preservation of equipment, tooling, and gauging;
e) applicable customer-specific requirements;
f) documented objectives. (e.g. OEE – Overall equipment effectiveness, MTBF – Mean Time Between Failure, MTTR – Mean Time To Repair), and preventive maintenance compliance metrics. Performance for maintenance objectives forms an input into management review.
g) regular review of maintenance plan and objectives, corrective actions when objectives are not achieved;
h) use of preventive maintenance methods;
i) use of predictive maintenance methods (as applicable);
j) periodic overhaul.

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

We control tool in accordance with defined procedure including the following:

a) tool maintenance and repair and personnel;
b) storage and recovery;
c) set-up;
d) tool-change programmes for perishable tools (list, frequency);
e) records of tool changes (including tool design);
f) tool rework and revision to documentation;
g) tool status (such as production, repair or disposal), identification related ownership and location (such as serial or asset number);

We confirm that customer-owned tools, manufacturing equipment, and test/inspection equipment are marked by marking and plate in a visible location so that the owner and application objectives can be determined.

We monitor these activities if above work is outsourced.

8.5.1.7 Production scheduling

We ensure that:

- Make a production plan to meet customer orders;
- Establish an information system that permits access to production information at key stages of the process;
- Manufacture based on orders.

Production scheduling includes below information:
(customer orders, supplier delivery performance, capacity, multi-part machining equipment, lead time, inventory level, preventive maintenance, and calibration)

8.5.2 Identification and traceability

We identify the product by suitable means throughout product realization, inspection and shipment. If the method of traceability is designated by the customer, it shall be applied otherwise procedure for lot control shall be applied. The records shall be maintained.

8.5.2.1 Identification and traceability – supplemental

We implement traceability as described below to identify clear start and stop points of production for product delivered to the customer or in the field that may certain quality and/or safety-related nonconformities.

We conduct an analysis of in-house, customer and regulatory traceability requirements for all automotive products, including developing and consider whether if it can be react or not,

The appropriate traceability methods are defined by product, process, and manufacturing location that:

a) identification of non-conforming and suspect parts;
b) segregation of non-conforming and suspect parts;
c) ensure the ability to meet the customer and/or regulatory lot tracking time requirements;
d) retain the records in the format (electronic data, paper) that enables us to meet the lot tracking time requirements;
e) serialized identification of individual products (if specified by the customer or regulatory standards);
f) ensure the identification and traceability requirements are applied to provide products by supplier with safety/regulatory characteristics.

8.5.3 Property belonging to customers or external providers

We exercise care with customer and external provider property as well as our product

while it is under our control or being used by us. Customer and external provider property provided for use or incorporation into the product shall be identified, verified, protected and safeguarded. If any customer and external provider property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and external provider, and records maintained. (Customer and external provider property can include intellectual property, material, parts, tool, equipment, facility, and personal information such as "Drawing" and "Specification".)

8.5.4 Preservation

We preserve products in a state of conforming with customer requirements during internal processing and delivery to the customer. This preservation shall include identification, handling, pollution prevention, packaging, storage, protection and shipment. Preservation shall also apply to the constituent parts of a product.

8.5.4.1 Preservation – supplemental

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

In order to detect product deterioration, assess the condition of product in stock, the place/type of container, and the storage environment at shipment and stocktaking.

We use a system to optimize inventory turns over time and ensure stock rotation. We ensure "first-in-first-out" (FIFO) of products. We treat obsolete product as defect product. We comply with customer requirements of preservation, packaging, shipping, and labeling.

8.5.5 Post-delivery activities

We meet requirements for post-delivery activities associated with the products. In determining the extent of post-delivery activities that are required, we consider:

a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its products;
c) the nature, use and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback.

8.5.5.1 Feedback of information from service

When we receive field complaint information from customer, we establishes and uses process for communication on the information to relevant department for resource

improvement.

8.5.5.2 Service agreement with customer

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

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

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

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

8.5.6 Control of changes

We review and control change for production, to the extent necessary to ensure continuing conformity with requirements. We retain records of the results of the review of changes, the approval person of the change, and any necessary actions rising from the review.

We review and control change for production to the extent necessary to ensure continuing conformity with requirements.

8.5.6.1 Control of changes – supplemental

We have a process to control initial products for the changes of all processes of product realization, including these changes caused by customer requirements and supplier's process change. We shall:

a) define verification and validation activities to ensure compliance with customer requirements;
b) validate changes before implementation;
c) retain records of the evidence of related risk analysis;
d) retain records of verification and validation.

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

When required by the customer, we shall:

e) apply the customer of production realization process changes after the mass production start;
f) obtain documented customer approval, prior to implementation of the change;
g) complete additional verification or identification requirements, such as production trial run and new product validation.

8.5.6.1.1 Temporary change of process controls

We make, document and maintain a list of the process controls, including inspection, measuring, test, and error-proofing devices, that includes the primary process control and the approved back-up or alternate methods.

We have a documented process that manages the use of alternate control methods. We include in this process, based on risk analysis (such as FMEA), severity assessment, and the in-house approvals to be obtained prior to production implementation of the alternate control methods.

Before shipping product that was inspected or tested using the alternate method, we obtain approval from the customer(s) (if required). We maintain and periodically review a list of approved alternate process control methods that are descripted in the control plan.

Work standards for each alternate process control methods are prepared.

We review the operation of alternate process controls on a daily basis utilizing the following with the goal to return to the standard process as defined by the control plan as soon as possible.

a) daily quality focused audits (e.g., layered process audits)
b) chief meetings.

We confirm and retain records that all features of the error-proofing device or process are effectively reinstated for a defined period based on severity in the restart verification.

We ensure traceability of all products produced while any alternate process control method or processes are being used.

8.6 Release of products

We monitor and measures product characteristics at each process in accordance with "Work Standard", and record it including the acceptance judgement. Records shall be with signature or stamp of the person who authorizing the product release (pass through to next process or shipment), unless otherwise approved by a relevant authority and, as applicable, by the customer.

We retain records including the following on the release of products:

a) evidence of conformity with the acceptance criteria;
b) specification of the person authorizing the release.

8.6.1 Release of products – supplemental

We ensure the conformity with control plan. For initial release of products, we document that obtain in-house approval prior to the shipping. Control of initial products after mass production is according to Section 8.5.6.

8.6.2 Layout inspection and functional testing

We perform layout inspection (quality stocktaking) and a functional verification to applicable customer material standards and performance standards for each product, with frequency required by customer, as specified in the control plans. The result shall be applicable for review by customer.

8.6.3 Appearance items

We do not have "appearance items" designated by the customer.

When we start a production of "appearance items", each division prepare the followings:

a) inspection area, appropriate lighting installation
b) maintenance of appropriate surface condition of product sample and haptic technology, as appropriate (color, gross, grain, metallic brilliance, roughness, distinctness of image

(DOI);

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

d) verification that shipping inspector making appearance inspection is qualified to do so.

8.6.4 Verification and acceptance of conformity of externally provided product

Relevant division ensures the quality of externally provided processes and products utilizing one or more of the following items:

a) receipt and evaluation of periodic inspection data provided by the supplier (including statistical data);

b) receiving inspection (part name, quantity, appearance);

c) audits at suppliers (QAV-2) (records of quality performance of acceptable delivered products);

d) part evaluation by a designated laboratory;

e) another method agreed with the customer.

8.6.5 Statutory and regulatory conformity

Prior to the use of externally provided products, the organization shall confirm and be able to provide an evidence that materials of products do not contain certain toxic or hazardous substances specified in the latest statute, regulation, and other requirements in countries where they are manufactured and consumed.

8.6.6 Acceptance criteria

We shall clearly define acceptance criteria for product inspection in “Work Standards” and “Control Plan”. We shall apply zero defects as acceptance level concerning attribute-sampling plan.

Where customer requires, we shall submit control plan to customer and obtain approval.

8.7 Control of defect products

8.7.1 We identify and control defect products to prevent their unintended use or delivery to the customer. We take appropriate action based on the content of nonconformity and its effect on the conformity of products. This also applies to products after delivery to the customer.

We deal with defect products in one or more of the following ways:

a) correction;

b) segregation, mixing prevention, return and delivery stop of products

c) informing the customer;

d) obtaining authorization for delivery under concession.

Conformity to the requirements shall be verified when nonconforming are corrected (reworked).

8.7.1.1 Customer authorization for concession

We obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. We 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 is clearly communicated to the customer and implemented the concession or deviation permit.

We maintain a record of the deadline or quantity authorized under concession. We also ensure compliance with the original or superseding specifications and requirement when the authorization expires. At shipment of products under concession are properly identified. When supplier applies a concession, we submit it to the customer after obtaining approval of in-house.

8.7.1.2 Control of defect product – customer-specified process

We comply with customer-specified requirements for control of defect products.

8.7.1.3 Control of suspect product

We classify product with unidentified or suspect status as defect products. We implement for all manufacturing personnel to receive training for outflow prevention of suspect and defect products.

8.7.1.4 Control of reworked product

We implement risk analysis (such as FMEA) to assess risks in the rework process prior to a decision to rework the product. If required by the customer, we obtain approval from the customer prior to commencing rework of the product.

We perform quality confirmation of rework product based on work standards.

Instructions for disassembly or reworks of assembled product, including re-inspection and traceability requirements, are accessible to it in appropriate work place and are utilized by the appropriate personnel. We retain records including quantity, disposition content, disposition date and applicable traceability information when dispose reworked product.

8.7.1.5 Control of repaired product

We utilize risk analysis method (such as FMEA) to assess risks in the repair process prior to a decision to repair the product. We obtain approval from the customer before

commencing repair of the product.

We perform quality confirmation of rework product in accordance with work standards.

Instructions for disassembly or repair of assembled product, including re-inspection and traceability requirements, is accessible to and utilized by the appropriate personnel and at the appropriate workplace.

We obtain a documented customer authorization for concession for the product to be repaired.

We retain documented record on disposition of repaired product including quantity, disposition content, disposition date, and applicable traceability information when they dispose repaired product.

We retain documented record on disposition of repaired product including quantity, disposition content, disposition date, and applicable traceability information when they dispose repaired product.

8.7.1.6 Customer notification

We immediately notify the customer(s) in the event that defect product has been delivered to the customer and follow the customer's instruction. Detailed contents are reported by documentation after initial communication.

8.7.1.7 Defect product disposition

We dispose defect product not subject to rework or repair based on "Defect product handling procedure". We verify that the product to be scrapped is rendered unusable prior to disposal.

We do not divert defect product to other use without prior customer approval.

8.7.2 We retain records that:

a) describes content of the defect product;

b) describes content of the action taken;

c) describes content of any concessions

d) describes the responsibility and authority for the action of defect product.

9. Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

We determine:

a) what needs to be monitored and measured;
b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
c) when the monitoring and measuring shall be performed;
d) when the results from monitoring and measurement shall be analyzed and evaluated.

We evaluate the performance and the effectiveness of the QMS and retain records of the results.

9.1.1.1 Monitoring and measurement of manufacturing process

We perform process studies on all new manufacturing processes to verify process capability and reflect the result to procedures such as “Work Standards”.

We implement the product approval process of customer’s requirements and maintains the result. We include the following to the process flow diagram, PFMEA, and control plan.

a) measurement techniques;
b) sampling methods;
c) acceptance criteria;
d) measurement values and/or test results for variable data;
e) reaction plans and escalation route when acceptance criteria are not met.

We retain records of significant process events, such as tool change or machine repair.

We conduct a reaction plan indicated on the control plan for characteristics that are either not statistically capable or unstable.

These reaction plans include segregation of product and all (100 percent) inspection. We make and conduct a corrective action plan defined deadline and assigned responsibilities to ensure that the process becomes stable and capable.

When a customer requires a corrective action, we obtain customer’s review and approval.

We maintain records of effective dates of process changes.

9.1.1.2 Identification of statistical tools

Multidisciplinary team determines the appropriate statistical tools used in each process at the advanced product quality planning, as applicable. We verify that they are included in “D-FMEA”, “P-FMEA”, and “Control Plan”.

9.1.1.3 Application of statistical concepts

Following statistical concepts is understood and used by employees involved in the collection, analysis, and management of statistical data.

(Variation, control (stability), process capability, and the consequences of over-adjustment)

9.1.2 Customer satisfaction

We determine the methods for obtaining, monitoring and reviewing information of customer's perceptions of the degree to which their needs and expectations have been fulfilled.

9.1.2.1 Customer satisfaction – supplemental

We monitor customer satisfaction with us through continual evaluation of internal external performance indicators to ensure compliance to the product and process specifications and other custom requirements.

Performance indicators are based on objective evidence and include the following:

a) customer delivered part quality performance
b) customer's line stop
c) field returns, recalls, and warranty
d) delivery performance (including premium freight)
e) customer notifications including special status
(related to quality or delivery issues)

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

9.1.3 Analysis and evaluation

We analyze and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

a) conformity of products requirements;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the QMS;

d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the QMS.

9.1.3.1 Prioritization

Trends in quality and operational performance (productivity, quality defect cost, efficiency and effectiveness of processes) is compared with progress toward objectives of business plan,

9.1.3.1 Prioritization

Trends in quality operational performance (productivity, quality defect cost, efficiency and effectiveness of processes) is compared with progress toward objectives of business plan, then utilize support activities for priority

9.2 Internal audit

9.2.1 We plan and conduct internal quality audit at planned intervals to provide information on whether the QMS:

a) conforms to:
1) our own requirements for its QMS;
2) the requirements of IATF 16949.
b) is effectively implemented and maintained.

9.2.2 We include the following to internal audit process:

a) Establish and implement an audit programme(s) including the frequency, methods, responsibilities, important check item and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the each site, and the results of previous audits;
b) define the audit criteria and scope for each audit;
c) not conduct audit of own division to ensure objectivity and the impartiality of the audit;
d) report the results of the audits to quality assurance responsible person;
e) take appropriate correction and corrective actions before deadline;
f) retain records of audit results as report.

9.2.2.1 Internal audit planning

We have a documented internal audit process. The process include the development and implementation of an internal audit planning that covers the entire QMS including quality

management system audits, manufacturing process audits, and product audits.

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

The frequency of audits is reviewed and, where appropriate, adjusted based on occurrence of process changes, internal and external audit nonconformities, and/or customer delivered quality defects. The effectiveness of the internal audit result is reviewed as a part of management review.

9.2.2.2 Quality management system audit

We audit all QMS processes over each in the three-year audit cycle, according to an annual plan, to verify compliance with IATF 16949. We use the process approach for the audit. During the audit, we sample customer-specific QMS requirements to confirm the effective implementation.

9.2.2.3 Manufacturing process audit

We audit all manufacturing processes over each three-year calendar period to determine their effectiveness and efficiency determining using approach.

In case it has a customer specified requirement about process audit, we obey for that.

Within audit plan of each manufacturing process, includes all shifts and the appropriate sampling of the shift handover. The audit plan of each manufacturing process includes an audit of the effective implementation of the process risk analysis (such as P-FMEA), control plan, and associated documents.

9.2.2.4 Product audit

We audit products using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to product specified requirements. Where not defined by the customer, we define the approach to be used.

9.3 Management review

9.3.1 General

Quality responsible person of each site conduct the management review, with 1 time per year, to ensure that QMS is alignment with the achievement of quality policy and quality objective, and the strategic direction of the organization.

Also, the management review conducted will be report to the quality responsible person to

of MSI head of Quality Assurance Div.

9.3.1.1 Management review – supplemental

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

9.3.2 Management review inputs

We collects below information and input to the management review:

a) follow up for the result of previous management review;
b) changes in external and internal issues that are relevant to the QMS (if necessary GQM revision);
c) information on the performance and effectiveness of the QMS, including trends in:
    1) quality information and quality evaluation from customer;
    2) quality target and the performance;
    3) process performance and conformity of products;
    4) status of corrective actions;
    5) monitoring and measurement results;
    6) results of internal/external quality audits;
    7) the quality performance of suppliers;
d) the adequacy of resources;
e) the effectiveness of actions taken to address risks and opportunities (see Section 6.1);
f) opportunities for improvement.

9.3.2.1 Management review inputs – supplemental

Input to management review includes:

a) cost of poor quality (cost of internal and external nonconformance);
b) indicators of process effectiveness;
c) indicators of process efficiency;
d) product conformance;
e) assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1);
f) customer satisfaction (see Section 9.1.2);
g) review of performance against maintenance objectives;
h) warranty performance (where applicable);
i) review of customer scorecards (where applicable);

j) identification of potential field failures identified through risk analysis (such as FMEA);
k) actual occurred field failures and their impact on safety or the environment.

9.3.3 Management review outputs

Quality responsible person of each site instructs to each general managers considering the outputs of the management review, include decisions and actions related to:

a) opportunities for improvement;
b) any need for changes to the QMS;
c) resource needs.

We retain records of the result of management reviews.

9.3.3.1 Management review outputs – supplemental

Quality responsible person of each site instruct to make and promote an action plan when customer quality performance target are not met.

10 Improvement

10.1 General

We determine and implement actions including the following to meet customer requirement and enhance customer satisfaction.

a) improving products and services to meet requirements as well as to address future needs and expectations;
b) correcting, preventing or reducing undesired effects;
   1) reviewing the nonconformity and analyzing the cause;
   2) determining the occurrence/outflow cause of the nonconformity;
   3) determining if similar nonconformities could potentially occur again;
c)

10.2 Nonconformity and corrective action

10.2.1 When in-process defect and customer delivered defect occurs, we:

a) react, as applicable:
 1) identify and control to avoid unintended use and shipment of defect products, and take an action to correct it;
 2) deal with (e.g. sorting) the impact that the nonconformity impacts on the customer.
b) To prevent the nonconformity does not recur or occur elsewhere, by take measures to eliminate the cause by the following matters
   1) reviewing and analyzing the nonconformity;
   2) determining the causes of the nonconformity;
   3) determining if similar nonconformities exist,
      or could potentially occur;
c) implement measures, reoccurrence prevention and horizontal development needed;

d) verify the effectiveness of any corrective action taken;
e) update risks and opportunities determined during establishing the QMS, if necessary;
f) review the QMS, if necessary.

10.2.2 We retain records as evidence of:
a) the content of the nonconformities and any subsequent actions taken;
b) the results of any corrective action.

10.2.3 Problem solving

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

a) defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);
b) outflow prevention, interim actions, and related activities necessary for control of defect products;
c) root cause analysis, methodology used, analysis, and results;
d) implementation of reoccurrence prevention and horizontal development
e) verification of the effectiveness of implemented corrective actions;
f) reviewing and, where necessary, updating PFMEA, control plan and work standards.

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

10.2.4 Pokayoke

We have a documented process for the use of appropriate pokayoke. Details of the pokayoke used are documented in P-FMEA and test frequencies are documented in the control plan.

The process includes the testing of pokayoke devices for failure or simulated failure. Records are maintained. Pokayoke master is identified, controlled, verified, and calibrated. We make a reaction plan when pokayoke device failure occurred.

10.2.5 Warranty management systems

When we are required to provide warranty for each site product(s), we implement a warranty management process. We include in the process a method for warranty part analysis, including NTF (no trouble found). When specified by the customer, we implement the required warranty management process.

10.2.6 Customer complaints and field failure test analysis

We perform analysis on returned parts from customer's manufacturing plant, technical division and service division. We retain the result of analysis and submit it when customer required. We start a corrective action to prevent reoccurrence in accordance with the result of analysis.

We perform analysis on delivered defects and filed failures, including any returned parts, and determine route cause and initiate corrective action to prevent reoccurrence.

We communicate the results of test/analysis to the customer and also within in-house relevant division.

We consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs that shall be addressed to measures for business plan.

10.3 Continual improvement

We continually improve the suitability, adequacy and effectiveness of the QMS.
We consider if there are needs that the results of analysis and assessment, and the outputs from management review shall be addressed as actions of business plan.

10.3.1 Continual improvement – supplemental

We have a documented process for continual improvement, including the following:

a) identification of the method used, objectives, measurement, effectiveness, and records;
b) a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;
c) risk analysis (such as FMEA).

Revision History

Established revised	Version	Description	Approval	Audited	Prepared
1/Nov/2019	1	Establishment		Muramatsu	Midori