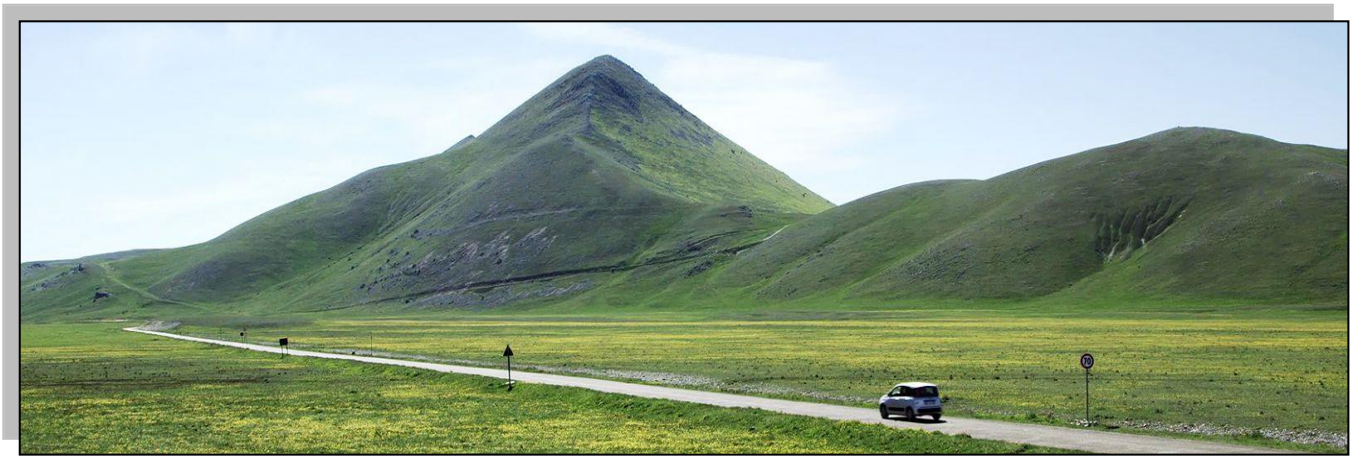
DENSO

Supplier Quality Assurance Manual

for parts and raw materials



The DENSO Philosophy guides our corporate actions, ensuring that we will continue to be trusted by people around the world. Our vision is for a safer and more eco-friendly future with fewer accidents.

Everything we do is based on our philosophy:

"Contributing to a better world by creating value together with a vision for the future."

Kim Buhl	Pat Bassett
VP - Purchasing	Sr. VP - Quality Engineering
Approvals	

Table of Contents:

9/2024 Change-Points (blue header indicates the whole section is new)

I. Introduction and General Information

I.a. Introduction to the DENSO Supplier Quality Assurance Manual (SQAM)

TOC

Purpose:
To provide basic information about DENSO to its suppliers and to outline the Supplier Quality Assurance Process as communicated through the SQAM.
Scope:
This SQAM applies to all external suppliers of production parts and raw materials to DENSO. Some examples of production parts: software components, micro controllers, hardware parts, molded components, etc.
Link to ISO / MAQMSR:
N/A
Documents related:
N/A

Explanation:

DENSO Quality Policy:
To be the supplier of choice for all our customers through customer satisfaction by continuously improving the quality of our products and services.

Supplier Responsibilities:

1. DENSO and its Customers expect "zero defects" and DENSO recognizes the importance of its suppliers in providing DENSO with quality parts and raw materials on time, so that those Customer's expectations can be met.

DENSO requires all suppliers of automotive products and services to develop, implement, and improve a quality management system (QMS) with the ultimate objective of eligible organizations becoming certified to this Automotive QMS Standard. Unless otherwise authorized by the customer, a QMS certified to ISO 9001 is the initial minimum acceptable level of development. Based on current performance and the potential risk to the customer, the objective is to move suppliers through the following QMS development progression:

Disclaimer: Sanctioned interpretation removed

a) Certification to ISO 9001 through third-party audits; unless otherwise specified by the customer, suppliers to the organization shall demonstrate conformity to ISO 9001 by maintaining a third-party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA member and where the accreditation body's main scope includes management system certification to ISO/IEC 17021;
b) Certification to ISO 9001 with compliance to other customer-defined QMS requirements (such as Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers [MAQMSR] or equivalent) through second-party audits;
c) Certification to ISO9001 with compliance to IATF 16949 through second-party audits;
d) Certification to 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body).

NOTE: The minimum acceptable level of QMS development may be compliance to ISO 9001 through second-party audits, if authorized by the customer.

1. The supplier shall immediately inform DENSO when their ISO 9001 or IATF 16949 certification (certificate) is lost, suspended, revoked, expired or designated on special status
2. ISO 14001 certification is encouraged.
3. Open Communication Philosophy:

a) Suppliers are a very important part of DENSO and good communications are critical to building an effective relationship. By following the standardized supplier quality assurance procedures outlined in this SQAM, supplier issues affecting product quality, service, and delivery can be controlled to eliminate any possible negative effect to DENSO Customers.
b) It is critical that suppliers become fully knowledgeable of the SQAM so that they understand how, when, and why submissions and documentation are provided to DENSO.

c) DENSO strives for effective and positive relationships with its suppliers. Suppliers are encouraged to contact their assigned Supplier Quality Representative whenever clarification is needed about the SQAM or if the supplier foresees some problem in being able to meet the SQAM. Early effective communication can help resolve issues before they become a problem.

NOTE: For this new revision of DENSO North America Supplier Quality Assurance Manual, requirements from IATF 16949:2015 have been integrated. These requirements are part of MAQMSR (Minimum Automotive Quality Management System Requirements) required by subscribed customers.

I.b DENSO Site Safety and Security Guidelines for Visiting Suppliers

TOC

Purpose:
DENSO is committed to maintaining a safe and secure environment at all sites and expects all visiting suppliers to fully comply with company and governmental guidelines regarding safety and legal issues.
Scope:
These guidelines apply to all suppliers and suppliers' support personnel who visit DENSO sites.
Link to ISO / MAQMSR:
N/A
Documents related:
N/A

Explanation:
All suppliers and suppliers' support personnel are required to abide by the guidelines as put forth in this policy. If there are any questions about specific safety and security requirements, the DENSO host department and/or Safety, Health, and Environment should be contacted for clarification before the visit.
Supplier Responsibilities:

1. General Guidelines:

a) All suppliers and suppliers' support personnel are required to bring the appropriate safety equipment with them when they visit DENSO sites.

2. Safety glasses with side shields are required in the manufacturing areas (ANSI Z87).
3. Steel-toed safety shoes are required in the manufacturing areas.
4. Special shoe covers may be required at certain facilities, please check with your Quality Representative. These covers may be available at the Plant Security Office.
5. Protective equipment such as gloves, body suits, respirators, helmets, anti-static overcoats and earplugs may be required at these sites depending on the nature of the supplier's visit.
6. Any visitors who will be going into manufacturing areas must wear appropriate clothing. Examples of articles that might be inappropriate: scarves, ties, jewelry, etc. Shorts and open shoes are prohibited. DENSO host facility should convey additional site-specific requirements.
7. Suppliers, when handling the DENSO products or product information, shall keep them strictly confidential based on information terminology listed in the purchasing contract or agreement. Supplier shall keep information confidential that is related to any new products or parts under development.
8. No cameras or recording devices are allowed in DENSO facilities without the written approval by DENSO. Cell phones may not be permitted. Please check with your Quality Representative.
9. All DENSO manufacturing, office, and cafeteria areas are Smoke-Free. Some sites do have identified outside areas where Smoking is permitted.
10. All visitors must be accompanied by DENSO associates through the length of their tour and unless specific areas are indicated by the DENSO host visitors must stay within the marked aisle ways.
11. DENSO sites are production facilities with a variety of machinery and forklifts/overhead cranes being used. Please be alert to your surroundings.
12. DENSO sites have emergency plans to deal with emergencies. Should the alarm system go off during your visit, listen carefully to the instructions of your host and other DENSO personnel and go with them to the appropriate staging area they indicate.
13. Accident/ Injury Reporting:

a) In the event of an accident or injury, the DENSO host should immediately be aware of the incident as well as the Safety, Health, and Environment Department. If there is no immediate response, contact the Security Department.

b) Suppliers and supplier's support personnel must be covered under worker's compensation insurance. Proof of coverage may be requested during visits to DENSO facilities.

14. First Aid/ Emergency Medical Services:

a) DENSO facilities maintain First Aid Stations at each facility. Basic first aid, such as bandages, can be obtained at these stations.
b) In the event of an incident beyond basic first aid, DENSO will assist in arranging medical transportation to outside medical facilities as needed. All costs related to such transportation and medical treatment is understood as being the responsibility of the supplier.

15. Loss Prevention/ supplier use of own tools, gages, and parts at DENSO facilities:

a) Suppliers can bring in tools, gages, and parts. Any equipment that is not readily identifiable as being the property of the supplier must be put on an itemized list that states item type, manufacturer, and serial number that can be shown to the Security Department or DENSO host that establishes ownership of the equipment at the beginning of the visit. This list may be used when the supplier leaves the DENSO facility, they have been visiting to audit the removal of equipment.
b) Any equipment brought to DENSO facilities must be in safe working condition and operated by trained, competent, and, where applicable, certified operators.
c) Use of DENSO equipment is not permitted without prior written authorization from the DENSO host facility.

16. Chemical Usage by suppliers at DENSO facilities:

a) Suppliers may bring in chemicals necessary to their visit at DENSO, but all chemicals must be pre-approved by the Safety, Health, and Environment Department. The supplier is fully responsible for compliance with all laws regarding the transportation, packaging, storage, handling, and disposal of their hazardous materials. Chemical disposal shall be arranged with site host and/or SHE Department.

17. Legal Matters of Employment/ Sexual Harassment:

a) It is fully understood that any individual sent by a supplier to a DENSO facility is the employee of that supplier and that the supplier accepts full responsibility for that employee's actions while at a DENSO facility.
b) DENSO expects full compliance to all governmental and DENSO policies regarding fair employment practices and sexual harassment. DENSO is fully committed to a positive working environment.

18. Environmental Management System. All DENSO suppliers are strongly encouraged to establish an environmental management system based on the ISO 14001 standard.
19. Entry into DENSO

DENSO reserves the right to refuse entry of any person into a DENSO facility due to concerns regarding safety and/or security.

I.c Supplier Use of Workers for Temporary Service at DENSO

TOC

Purpose:
To define the requirements placed on suppliers when they have to use employees for temporary service at DENSO facilities.
Scope:
This process applies to all suppliers that are asked to correct problems with "suspect" production parts or raw materials which they have sent to DENSO.
Link to ISO / MAQMSR:
N/A
Documents related:
N/A

Explanation:
It is critical that only conforming materials be sent to DENSO. In the event of a problem occurring with a flow out of suspect product from the supplier to DENSO, it may be required that the supplier come on-site to the facility and arrange/carry out activities to correct the non-conformance. Each supplier's Quality Representative will communicate the necessity of such activities to the supplier.
Supplier Responsibilities:
1. In order to perform corrective actions at DENSO facilities, suppliers must obtain the approval of their Quality Representative and coordinate their activities through this representative. 2. Suppliers may use temporary service employees to support activities such as 100% inspection, sort, or rework of nonconforming parts. 3. Supplier representatives must develop and implement a plan that will ensure no flow out of nonconforming products to DENSO Customers. This includes proper coordination and training of their temporary service employees to achieve this expectation. Suppliers are fully responsible for the safety of their temporary service workers and the quality of their work (Ref. Section I.b - DENSO site safety and security guidelines for visiting suppliers). 4. Supplier's temporary service employees must have full-time supervision provided by the supplier unless otherwise approved by the DENSO Quality Representative. 5. As an alternative to direct supplier supervision of temporary workers, the supplier may use a DENSO preauthorized "full service" sorting company. To use this option, the supplier must contact the appropriate DENSO Quality Representative. Supplier representatives must develop and implement a plan that will ensure no flow out of nonconforming products to DENSO Customers. This includes proper coordination and training of the "full service" sorting company to achieve this expectation. Suppliers are fully responsible for the safety of the "full service" sorting company and the quality of their work (Reference Section I.b - DENSO site safety and security guidelines for visiting suppliers). 6. Suppliers are expected to begin certifying suspect parts at DENSO in an expeditious manner. In the event that suspect part certification is delayed due to a slow supplier response or a supplier in different time zone, DENSO reserves the right to hire a full service sorting company on behalf of that supplier. The supplier is expected to contact the full service sorting company as soon as possible in order to have the responsibility for sorting cost transferred from DENSO over to the responsible supplier.

I.d Fundamental requirements

TOC

Purpose:
To define the requirements placed on suppliers when they have to use employees for temporary service at DENSO facilities.
Scope:
This section applies to all suppliers of production parts and raw materials to DENSO.
Link to ISO / MAQMSR:
5.1.2 Customer focus / 5.2 Policy / 5.2.1 Developing the quality policy /5.2.2 Communicating the quality policy / 6.1, 6.1.1 Actions to address risks and opportunities / 6.2, 6.2.1, 6.2.2.1 Quality objectives and planning to achieve them / 7.1.3 Infrastructure / 7.1.4 Environment for the operation of processes / 7.1.5 Monitoring and measuring resources / 7.1.6 Organizational Knowledge / 7.3 Awareness / 8.1 Operational planning and control / 8.5 Production and service provision / 8.5.1 Control of production and service provision / 8.5.3 Property belonging to customers or external providers / 9.1, 9.1.1 Monitoring, measurement, analysis and evaluation.
Documents related:
N/A

Explanation:
In order to comply with ISO & MAQMSR, all requirements that are not belonging to a specific section of this manual, has been collected in one area. Supplier shall follow the requirements stated in this section.
Supplier Responsibilities:

[ISO]: Customer Focus

Supplier top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met.

b) 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 is maintained.

[ISO]: Developing the Quality Policy

Supplier top management shall establish, implement, and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction.

b) provides a framework for setting quality objectives.

c) includes a commitment to satisfy applicable requirements.

d) includes a commitment to continual improvement of the quality management system.

[ISO]: Communicating the quality policy

The quality policy shall:

a) be available and be maintained as documented information.

b) be communicated, understood and applied within the organization.

c) be available to relevant interested parties, as appropriate.

[ISO]: Actions to address risks and opportunities

When planning for the quality management system, the supplier shall consider the issues referred to in section I.f and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s).

b) enhance desirable effects.

c) prevent, or reduce, undesired effects.

d) achieve improvement.

The supplier shall plan:

a) actions to address these risks and opportunities.

b) how to:
1) integrate and implement the actions into its quality management system processes (section I.f)
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 products and services.
NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.
NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

[ISO & MAQMSR]: Quality objectives and planning to achieve them
The supplier shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.
The quality objectives shall:
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.
The supplier shall maintain documented information on the quality objectives.
When planning how to achieve its quality objectives, the organization 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.
[MAQMSR]: Supplier Top management shall ensure that quality objectives to meet DENSO requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization.
NOTE: The results of the supplier organization's review regarding interested parties and their relevant requirements shall be considered when the organization establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).

[ISO]: Infrastructure
The supplier shall determine, provide, and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.
NOTE Infrastructure can include:
a) buildings and associated utilities.
b) equipment, including hardware and software.
c) transportation resources.
d) information and communication technology.

[ISO]: Environment for the operation of processes
The supplier shall determine, provide, and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.
NOTE A suitable environment can be 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).

These factors can differ substantially depending on the products and services provided.

[ISO]: Monitoring and measuring resources

The supplier shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.
The supplier shall ensure that the resources provided:
a) are suitable for the specific type of monitoring and measurement activities being undertaken.
b) are maintained to ensure their continuing fitness fory their purpose.
The supplier shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

[ISO]: Organizational Knowledge

The supplier shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.
This knowledge shall be maintained and be made available to the extent necessary.
When addressing changing needs and trends, the supplier shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.
NOTE 1 Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization's objectives.
NOTE 2 Organizational knowledge can be based on:

a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);
b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

[ISO]: Awareness

The supplier shall ensure that persons doing work under the organization's control are aware of:

a) Relevant quality objectives.
b) their contribution to the effectiveness of the quality management system, including the benefits of improved performance.
c) the implications of not conforming with the quality management system requirements.

[ISO]: Operational planning and control

The supplier shall plan, implement, and control the processes (section I.f) needed to meet the requirements for the provision of products and services, and to implement the actions determined in clauses 6.1 Actions to address risks and opportunities and 6.2 Quality objectives and planning to achieve them, by:
a) determining the requirements for the products and services.
b) establishing criteria for:
1) the processes.
2) the acceptance of products and services.
c) determining the resources needed to achieve conformity to the product and service requirements.
d) implementing control of the processes in accordance with the criteria.
e) determining and keeping documented information to the extent necessary:
1) to have confidence that the processes have been carried out as planned.
2) to demonstrate the conformity of products and services to their requirements.
NOTE "Keeping" implies both the maintaining and the retaining of documented information.
The output of this planning shall be suitable for the organization's operations.
The supplier shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.
The supplier shall ensure that outsourced processes are controlled (see section IV.i).

[ISO]: Production and service provision

Control of production and service provision

The supplier shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

a) Availability of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed.

2) the results to be achieved.

b) the availability and use of suitable monitoring and measuring resources.

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met.

d) the use of suitable infrastructure and environment for the operation of processes.

e) the appointment of competent persons, including any required qualification.

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

g) the implementation of actions to prevent human error.

h) the implementation of release, delivery and post-delivery activities.

[ISO]: Property belonging to customers or external providers

The supplier shall exercise care with property belonging to customers or external providers while it is under the supplier's control or being used by the supplier.

The supplier shall identify, verify, protect, and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the supplier shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

[ISO]: Monitoring, measurement, analysis and evaluation

The supplier shall 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. The supplier shall evaluate the performance and the effectiveness of the quality management system. The supplier shall retain appropriate documented information as evidence of the results.

I.e Understanding the organization and its context

TOC

Purpose:
The supplier shall 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.
Scope:
This section applies to suppliers of products and/or services sent to DENSO.
Link to ISO / MAQMSR:
4.1 Understanding the organization and its context, 4.2 Understanding the needs and expectations of interested parties
Documents related:
N/A

Explanation:
[ISO]: The supplier shall monitor and review information about external and internal issues. NOTE 1 Issues can include positive and negative factors or conditions for consideration. NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the supplier organization.
Supplier Responsibilities:
[ISO]: Due to their effect or potential effect on the supplier's ability to consistently provide products and services that meet DENSO and applicable statutory and regulatory requirements, the supplier shall determine: a) the interested parties that are relevant to the quality management system. b) the requirements of these interested parties that are relevant to the quality management system. The supplier shall monitor and review information about these interested parties and their relevant requirements.

I.f Quality Management Systems

TOC

Purpose:
To establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of DENSO Supplier Quality Assurance Manual.
Scope:
This section applies to suppliers of products and/or services sent to DENSO.
Link to ISO / MAQMSR:
4.3 Determining the scope of the Quality Management System / 4.4, 4.4.1, 4.4.2 Quality Management System / 6.3 Planning of changes
Documents related:
N/A

Explanation:
The supplier shall determine the boundaries and applicability of the quality management system. When determined the supplier shall consider: a) the external and internal issues that are relevant to its purpose and its strategic direction. b) the requirements of relevant interested parties. c) the products and services of the organization.
Supplier Responsibilities:
[ISO]: 1. The supplier shall determine the processes needed for the quality management system and their application throughout the organization, and shall: a) determine the inputs required and the outputs expected from these processes. b) determine the sequence and interaction of these processes. c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes. 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 clause 6.1 Actions to address risks and opportunities. g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results. h) improve the processes and the quality management system. **[ISO]:** To the extent necessary, the supplier shall: a) maintain documented information to support the operation of its processes. b) retain documented information to have confidence that the processes are being carried out as planned. **[ISO]: 2. Planning of changes in the Quality Management System** When the supplier determines the need for changes to the quality management system, the changes shall be carried out in a planned manner. The supplier shall consider: a) the purpose of the changes and their potential consequences. b) the integrity of the quality management system. c) the availability of resources. d) the allocation or reallocation of responsibilities and authorities.

I.g Management Review

TOC

Purpose:
To ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of organization, suppliers' top management shall review the organization's quality management system, at planned intervals.
Scope:
This section applies to suppliers of products and/or services sent to DENSO.
Link to ISO / MAQMSR:
9.3, 9.3.1, 9.3.1.1 Management Review / 9.3.2, 9.3.2.1 Management review inputs / 9.3.3, 9.3.3.1 Management review outputs / 5.1.1.2 Process effectiveness and efficiency
Documents related:
N/A

Explanation:
Management review shall be conducted at least annually. The frequency of management review(s) shall be increased based on risks to compliance with DENSO requirements resulting from internal or external changes impacting the quality management system and performance-related issues.
Supplier Responsibilities:

Management review Inputs

[ISO] The management review shall be planned and carried out taking into consideration:

a) the status of actions from previous management reviews.

b) changes in external and internal issues that are relevant to the quality management system.

c) information on the performance and effectiveness of the quality management system, including trends in:

1) customer satisfaction and feedback from relevant interested parties.

2) the extent to which quality objectives have been met.

3) process performance and conformity of products and services.

4) nonconformities and corrective actions.

5) monitoring and measurement results.

6) audit results.

7) the performance of external providers.

d) the adequacy of resources.

e) the effectiveness of actions taken to address risks and opportunities (see ISO 9001 6.1 Actions to address risks and opportunities).

f) opportunities for improvement.

[MAQMSR] Input to management review shall include:

a) cost of poor quality (failure, appraisal, and prevention).

b) measures of process effectiveness.

c) measures of process efficiency for product realization processes, as applicable.

d) product conformance.

e) plant, facility, and equipment planning to ensure manufacturing feasibility made for changes to existing operations and for new facilities or product.

f) customer satisfaction (see ISO 9001, Section 9.1.2 Customer satisfaction).

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 field failures and their impact on safety or the environment.

l) summary results of measurements at specified stages during the design and development of products and processes, as applicable.

[ISO] Management review outputs
The outputs of the management review shall include decisions and actions related to:
a) opportunities for improvement.
b) any need for changes to the quality management system.
c) resource needs. The supplier shall retain documented information as evidence of the results of management reviews.
[MAQMSR] Suppliers' Top management shall document and implement an action plan when customer performance targets are not met.

I.h Organizational roles, responsibilities, and authorities

TOC

Purpose:
Suppliers' top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization.
Scope:
This section applies to suppliers of products and/or services sent to DENSO.
Link to ISO / MAQMSR:
5.1, 5.1.1 Leadership and commitment / 5.3 Organizational roles, responsibilities, and authorities / 5.3.1 Organizational roles, responsibilities, and authorities / 5.3.2 Responsibility and authority for product requirements and corrective actions / 5.1.1.1 Corporate responsibility / 7.1 Resources / 7.1.2 People / 7.2 Competence
Documents related:
N/A

Explanation:
Suppliers' top management shall assign personnel with the responsibility and authority to ensure that customer requirements are met. These assignments shall be documented. This includes but is not limited to the selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards, and customer portals.
Supplier Responsibilities:
[ISO]: Leadership responsibilities and commitment Suppliers' top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system. b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the supplier organization. c) ensuring the integration of the quality management system requirements into the supplier organization's business processes. d) promoting the use of the process approach and risk-based thinking. e) ensuring that the resources needed for the quality management system are available. f) communicating the importance of effective quality management and of conforming to the quality management system requirements. g) ensuring that the quality management system achieves its intended results. h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system. i) promoting improvement. j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. **[MAQMSR]:** k) Supplier corporate shall define and implement corporate responsibility policies, including at a minimum an anti-bribery policy, an employee code of conduct, and an ethics escalation policy ("whistle-blower policy"). **[MAQMSR]: Responsibility and authority for product requirements and corrective actions** Suppliers' top management shall ensure that: a) personnel responsible for conformity to product requirements have the authority to stop shipment and stop production to correct quality problems. NOTE: Due to the process design in some industries, it might not always be possible to stop production immediately. In this case, the affected batch must be contained and shipment to the customer prevented. b) personnel with authority and responsibility for corrective action are promptly informed of products or processes that do not conform to requirements to ensure that non-conforming product is not shipped to the customer and that all potential non-conforming product is identified and contained.

c) production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.

[ISO]: Resources
The supplier shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.
The supplier shall consider:
a) the capabilities of, and constraints on, existing internal resources.
b) what needs to be obtained from external providers.
[ISO]: NOTE: The supplier shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.
Also, suppliers' top management shall assign the responsibility and authority for:
a) Ensuring that the quality management system conforms to the requirements of this manual.
b) Ensuring that the processes are delivering their intended outputs.
c) Reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management.
d) Ensuring the promotion of customer focus throughout the organization.
e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

[ISO]: Competence
The supplier shall:
a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system.
b) ensure that these persons are competent on the basis of appropriate education, training, or experience.
c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken.
d) retain appropriate documented information as evidence of competence.
NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re- assignment of currently employed persons; or the hiring or contracting of competent persons.

I.i Internal Audits

TOC

Purpose:
To confirm conformance of effectiveness and implementation to ISO & MAQMSR requirements.
Scope:
This section applies to suppliers of products and/or services sent to DENSO.
Link to ISO / MAQMSR:
9.2, 9.2.2 Internal audit / 9.2.2.1 Internal audit program / 9.2.2.2 Quality management system audit / 9.2.2.3 Manufacturing process audit / 9.2.2.4 Product Audit / 7.2.3 Internal Audit Competency.
Documents related:
N/A

Explanation:
The supplier shall conduct internal audits at planned intervals to provide information on whether the quality management system is effectively implemented and maintained and conforms to the organization's own requirements for its quality management system and the requirements of ISO 9001:2016 and MAQMSR.
Supplier Responsibilities:

[ISO]: The supplier shall:
a) plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits.
b) define the audit criteria and scope for each audit.
c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process.
d) ensure that the results of the audits are reported to relevant management.
e) take appropriate correction and corrective actions without undue delay.
f) retain documented information as evidence of the implementation of the audit program and the audit results.

[MAQMSR]: Internal Auditor Competency
The supplier shall have a documented process(es) to verify that internal auditors are competent, taking into account any requirements defined by the organization and/or customer-specific requirements. For additional guidance on auditor competencies, refer to ISO 19011. The organization shall maintain a list of qualified internal auditors.

Quality management system auditors shall be 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.
At a minimum manufacturing process auditors shall demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan.
At a minimum, Product auditors shall demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity.
If the organization's personnel provide the training to achieve competency, documented information shall be retained to demonstrate the trainer's competency with the above requirements.
Maintenance of and improvement in internal auditor competence shall be demonstrated through:
f) executing a minimum number of audits per year, as defined by the organization; 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).

[MAQMSR]: Internal Audit Program

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

[MAQMSR]: Quality management system audit

The supplier shall audit all quality management system processes over a three-year audit cycle, according to an annual programme, using the process approach to verify compliance with this Automotive QMS Standard. Integrated with these audits, the organization shall sample customer-specific quality management system requirements for effective implementation.
The complete audit cycle remains three years in length. The quality management system audit frequency for individual processes, audited within the three-year audit cycle, shall be based upon internal and external performance and risk. Organizations shall maintain justification for the assigned audit frequency of their processes. All processes are required to be sampled throughout the three-year audit cycle and audited to all applicable requirements in the IATF 16949 standard, including ISO 9001 base requirements, and any DENSO specific requirements.

[MAQMSR]: Manufacturing process audit

The supplier shall audit all manufacturing processes over each three-year calendar period to determine their effectiveness and efficiency using customer-specific required approaches for process audits. Where not defined by customer, the organization shall determine the approach to be used.
Within each individual audit plan, each manufacturing process shall be audited on all shifts where it occurs, including the appropriate sampling of the shift handover.
The manufacturing process audit shall include an audit of the effective implementation of the process risks analysis (such as PFMEA), control plan, and associated documents.

[MAQMSR]: Product audit

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

I.j Supplier Quality Performance Monitoring System

TOC

Purpose:
To provide a comprehensive evaluation system used to monitor supplier performance based on a variety of metrics, such as quality, cost, delivery, service, **[MAQMSR]:** customer disruptions, field returns, recalls, and warranty (where applicable), delivery schedule performance (including incidents of premium freight), customer notifications related to quality or delivery issues, including special status. These metrics are used for supplier management and to determine if any corrective action is necessary.
Scope:
This section applies to all suppliers of production parts and raw materials to DENSO.
Link to ISO / MAQMSR:
9.1.2 Customer Satisfaction / 9.1.2.1 Customer Satisfaction – supplemental / 9.1.3 Analysis and evaluation.
Documents related:
N/A

Explanation:
The Supplier Performance Monitoring system evaluates suppliers from a total perspective by utilizing direct input from the Quality, Production Control and the Purchasing departments. Supplier assessments are published monthly in the DENSO Supplier Portal system by the responsible buyer, planner and quality engineer based on previous month's quality, delivery and purchasing performance data. Each section is calculated using a 100 point system and weighted equally in determining the overall performance score.
Supplier Responsibilities:
[ISO]: The supplier shall analyze and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate: a) conformity of products and services. b) the degree of customer satisfaction. c) the performance and effectiveness of the quality management system. 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 quality management system. **NOTE** Methods to analyze data can include statistical techniques. **Corrective Actions** ▪ Suppliers who receive a delivery score below 70 are issued a DPIR (Delivery Product Incident Report) and are required to complete a corrective action request within the DENSO Supplier Portal system. DENSO Production Control is responsible for final DPIR approval. ▪ Suppliers who require a Corrective Action due to unacceptable quality performance will be managed directly with the appropriate DENSO Quality department. ▪ Suppliers who receive an overall performance score below 70 are required to acknowledge their score within the DENSO Supplier Portal. ▪ Suppliers who receive an overall performance score below 70 for 3 consecutive months are issued a CAR (Corrective Action Request) and are required to submit the completed response within the DENSO Supplier Portal. DENSO Purchasing is responsible for final CAR approval in collaboration with Quality and Production Control departments as needed.

I.k Supplier Quality Assurance Contacts

TOC

Purpose:
DENSO views communications as being critical to ensuring a positive relationship with its suppliers. Good communication allows for easier understanding of new product start up and quicker resolution of potential problems that could affect our customers. This policy outlines the roles and responsibilities of supplier personnel pertaining to the SQAM and how these individuals are identified to DENSO.
Scope:
This section applies to suppliers of production parts and raw materials to DENSO.
Link to ISO / MAQMSR:
7.4 Communication
Documents related:
Supplier Contact Form

Explanation:
Supplier Quality Assurance Contacts are the main liaisons between the supplier and DENSO, and they are responsible for ensuring effective communications regarding issues of quality assurance within their department as well as other departments within their company. An up-to-date contact list will be provided by the supplier. Changes to the contact list must be communicated to the DENSO Quality Representative as they occur.
Supplier Responsibilities:
[ISO] The supplier shall determine the internal and external communications relevant to quality assurance process, including. a) on what it will communicate. b) when to communicate. c) with whom to communicate. d) how to communicate. e) who communicates.

I.l New Supplier Evaluation

TOC

Purpose:
This introduces prospective new suppliers to Quality Systems and Process audit procedure they will need to complete before becoming a DENSO supplier.
Scope:
This section applies to any potential supplier of production parts or raw material.
Link to ISO / MAQMSR:
N/A
Documents related:
New Supplier Evaluation Form

Explanation:
It is critical that DENSO and their suppliers have alignment for quality systems and quality management expectations. The new supplier assessment form is one tool used by DENSO to support this effort.
Supplier Responsibilities:
Some key items of the new supplier qualification process are as follows. 1. The evaluation form should be completed by the supplier before the audit but will not be considered complete without an onsite audit by DENSO QE. 2. In addition to the New Supplier Quality System Evaluation you may be subject to have a process specific audit completed at your facility. The process specific audit format will be slightly different depending on the DENSO NA group that is auditing you. 3. If assigned, you must complete critical action items listed on the evaluations before you will be eligible for supplier consideration. 4. In addition, to this QE evaluation, supplier will also be subject to an on-site initial assessment, conducted by DENSO Purchasing, Quality and Production Control. 5. DENSO Purchasing and supplier shall complete and execute a mutual Non-Disclosure Agreement.

I.m Continuous Improvement

TOC

Purpose:
DENSO suppliers must employ appropriate methods to generate continuous quality improvement within their organization even when cost, quality and delivery targets are being met.
Scope:
DENSO suppliers must employ appropriate methods to generate continuous quality improvement within their organization even when cost, quality and delivery targets are being met. This section applies to suppliers of production parts and raw materials to DENSO.
Link to ISO / MAQMSR:
10.3 Continual Improvement / 10.1 Improvement
Documents related:
N/A

Explanation:
The supplier is expected to conduct continuous improvement activities on their own initiative to improve quality systems, reduce defects, and improve delivery and cost. The goal of these activities is to eliminate the root cause of defects and inefficiencies that negatively impact operations. Examples of methods include formal employee quality circles, corrective action, innovation, suggestion programs, failure mode effect and analysis and annual project plans.
Supplier Responsibilities:
[ISO]: The supplier shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include: a) Improving products and services to meet requirements as well as to address future needs and expectations. b) Correcting, preventing or reducing undesired effects. c) Improving the performance and effectiveness of the quality management system. d) The supplier shall continually improve the suitability, adequacy and effectiveness of the quality management system. **[ISO]:** e) The supplier shall consider the outputs from management review (section I.g), to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

I.n Review of products and services requirements with supplier

TOC

Purpose:
The purpose of this section is to describe the review of product-related and services requirements with the supplier and other related DENSO departments.
Scope:
This section applies to suppliers of production and service parts, and raw materials when deemed necessary by the responsible DENSO division.
Link to ISO / MAQMSR:
4.4.1.2 Product Safety / 8.2, 8.2.1 Requirements for products and services / 8.2.2 Determining the requirements for products and services / 8.2.3, 8.2.3.1 Review the requirements related to products and services / 8.2.4 Change to requirements for products and services / 8.4.2.2 Statutory and regulatory requirements / 8.5.4 Preservation / 8.5.5 Post delivery activities / 8.4.2.3.1 Automotive product-related software or automotive products with embedded software.
Documents related:
N/A

Explanation:
[ISO]: When determining the requirements for the products and services to be offered to DENSO, the supplier shall ensure that the requirements for the products and services are defined. A review of the product-related requirements should take place between the responsible DENSO division and the supplier. The discussion points should include the following: 1. Product requirements, Inspection requirements, customer specific requirements etc. a) Additional examples of product requirements may include, but not be limited to: Product safety, performance requirements, functional safety, cybersecurity, quality standards, statutory or regulatory requirements, privacy, etc. 2. Any changes to the contract or changes to order requirements. 3. Supplier's capability to meet the requirements listed above.
Supplier Responsibilities:
[ISO]: Communication with DENSO shall include: a) providing information relating to products and services. b) handling enquiries, contracts or orders, including changes. c) obtaining customer feedback relating to products and services, including customer complaints. d) handling or controlling customer property. e) establishing specific requirements for contingency actions, when relevant. **[ISO]:** The supplier shall ensure that it has the ability to meet the requirements for products and services to be offered to DENSO. The supplier shall conduct a review before committing to supply products and services to a customer, to include: 1. Fully engage in the above discussion so that all requirements are understood (this discussion should happen prior to business award.) **[ISO]:** 2. Requirements specified by DENSO, including the requirements for delivery and post- delivery activities. 3. Requirements not stated by DENSO, but necessary for the specified or intended use, when known. 4. Statutory and regulatory requirements applicable to the products and services. 5. Contract or order requirements differing from those previously expressed, the supplier shall ensure that those previously defined are resolved. **NOTE:** For changes to requirements for products and services the organization shall establish, implement, and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. **[MAQMSR]: Product safety supplier responsibilities:**

The supplier shall have documented processes for the management of product-safety related products and manufacturing-processes which shall include but not be limited to the following, where applicable:
a) identification by the organization of statutory and regulatory product-safety requirements
b) customer notification of requirements in 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 at the point of manufacture.
f) special approval of control plans and process FMEAs
g) reaction plans (See Section 9.1.1.1 Monitoring and measurement of manufacturing process)
h) defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification
i) training identified by the supplier organization or customer for personnel involved in product-safety related products and associated manufacturing processes
j) changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product-safety from process and product changes
k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources.
l) product traceability by manufactured lot (at a minimum) throughout the supply-chain
m) lessons-learned for new product introduction.
Note: Special approval of safety related requirements or documents may be required by the customer or the organization's internal processes.

[MAQMSR]: Statutory and regulatory requirements
The supplier shall document their process to ensure that purchased products, processes, and services conform to the current applicable statutory and regulatory requirements in the country of receipt, the country of shipment, and the customer-identified country of destination, if provided.
If DENSO defines special controls for certain products with statutory and regulatory requirements, the supplier shall ensure they are implemented and maintained as defined, including at suppliers.

[ISO]: Preservation
The supplier shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.
NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

[ISO]: Post delivery activities
The supplier shall meet requirements for post-delivery activities associated with the products and services.
In determining the extent of post-delivery activities that are required, the organization shall consider:
a) statutory and regulatory requirements.
b) the potential undesired consequences associated with its products and services.
c) the nature, use and intended lifetime of its products and services.
d) customer requirements.
e) customer feedback.
NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

[MAQMSR]: Automotive product-related software or automotive products with embedded software
This requirement applies to suppliers and their suppliers of automotive product-related software, or automotive products with embedded software, to implement and maintain a process for software quality assurance for their products.

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

II. Quality Assurance in Pre Mass Production

II.a Notification of Quality Assurance Requirements (NQAR)

TOC

Purpose:
Suppliers are notified of DENSO product submission requirements utilizing the NQAR. This includes detailed expectations of any and all trial part submissions prior to PPAP approval and identifies part or material critical product characteristics.
Scope:
Suppliers are notified of specific quality assurance requirements utilizing the NQAR form when a supplier is new or a current supplier with a new part number. These requirements are communicated after DENSO drawing release and prior to shipment of the initial samples. An NQAR may also be issued after an Engineering or Process Change. Unless parts/materials are similar and have the same requirements, one NQAR will be issued per part number.
Link to ISO / MAQMSR:
8.2.1 Customer communication
Documents related:
NQAR Form

Explanation:
The Notification of Quality Assurance Requirements (NQAR) informs the supplier of quality assurance requirements necessary for DENSO approval of parts/ material prior to PPAP. **[ISO]:** Communication with DENSO shall include: a) providing information relating to products and services. b) handling enquiries, contracts or orders, including changes. c) obtaining customer feedback relating to products and services, including customer complaints. d) handling or controlling customer property. e) establishing specific requirements for contingency actions, when relevant.
Supplier Responsibilities:
1. DENSO will issue the NQAR to the supplier and indicate due dates for each requirement. The supplier should use the last column of the NQAR (SUBMISSION DATE) to help track actual submission dates for each requirement. 2. When the supplier receives the NQAR, each requirement should be reviewed thoroughly to determine if the requirements are feasible and/or understood. Any concerns or questions about the requirements should be discussed with your DENSO Quality Representative. Once agreed and understood, provide a signed copy of the NQAR to your DENSO Quality Representative. 3. Suppliers are required to use forms for PPAP as mentioned at the bottom of each applicable section. Refer to the sections that outline each requirement in this manual. 4. DENSO designates the items in the table on the NQAR form as critical part or material characteristics that should be controlled in the supplier's process. The supplier should develop Inspection Standards and Process Control Instructions to give special attention to these items in addition to any items critical to the supplier's process. A Process Capability Study is required for the critical characteristics as indicated on the NQAR.

II.b New Product Development Planning

TOC

Purpose:
The purpose of this section is to explain the requirements, information and submission procedure for the planning of new product or material.
Scope:
This section applies to suppliers of production parts and raw materials when specified by DENSO.
Link to ISO / MAQMSR:
8.5 Production and service provision
Documents related:
QAS TPR – New Product Development Plan Form

Explanation:
DENSO product and/or material requirements may be based on key OEM schedule milestones including other OEM and DENSO special requirements. DENSO requires suppliers to use project planning to assure key milestone dates are met. Suppliers shall report project planning schedules and tooling status as requested by DENSO using the format specified by your DENSO representative. The New Product Development schedule shall be used by the supplier to provide DENSO with a schedule of all activities from issuing of the PO to initial mass production.
Supplier Responsibilities:
1. Quality Assurance Schedule (QAS) The supplier must create and submit a new product schedule on the DENSO requested format outlining activities required to support meeting customer milestones, including designated production trial builds to support SOP, advanced quality planning activities (reference AIAG APQP Manual), personnel training, and corresponding sub-component activities (if applicable). This schedule shall be submitted to DENSO by the due date. Schedules will be reviewed and adjustments negotiated as needed. 2. Tooling Status Reporting: Tooling scheduling and status reporting shall be included in the new product development schedule indicated above. DENSO may request a separate Tooling Progress Report which shall also include sub-supplier tooling (if applicable). For die making at external tool shop, it's the supplier's responsibility to assure that: 1) All trials are made using production intended material from the production intended source. It is supplier's responsibility to document and communicate all material used during trials at tool shop with DENSO representative. 2) All critical items are within specification before proceeding with tool transfer to final location. If there are any items out of specification (critical or non-critical), supplier must contact DENSO representative and obtain design section approval for transfer. 3. Supplier Review and Approval Requirements The new product development schedule including tooling, should be reviewed and approved by related departments. It is the responsibility of the supplier's related management to monitor schedule attainment and ensure all milestones are achieved. 4. Schedule Updates Any delay that could jeopardize reaching the customer milestones should be reported to your DENSO representative immediately. Timing for regular status reporting and format will be communicated to you by your DENSO representative. 5. New Product / New Business Consideration DENSO will cascade OEM requirements for new business. Applicable DENSO & OEM specific requirements are found in RFQ documents.

II.c Process Capability Requirements

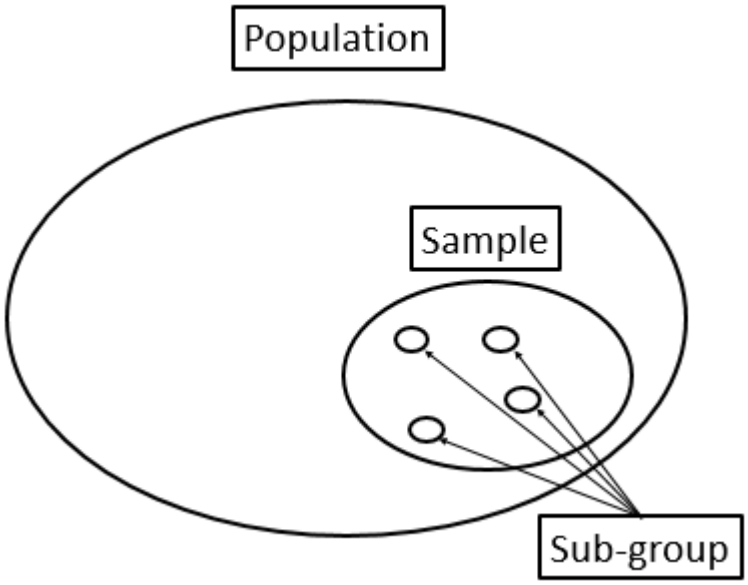
TOC

Purpose:
Define the requirements for Product Characteristics and their associated capability to DENSO suppliers.
Scope:
This section applies to suppliers of production parts and raw materials when specified on drawings, specifications, and/or the NQAR. The capability requirements cover both initial and ongoing process capability activities for critical and non-critical control characteristics.
Link to ISO / MAQMSR:
9.1.1.1 Monitoring and measurement of manufacturing process
Documents related:
N/A

Explanation:
Non-critical control characteristics require normal care to assure conformance to specifications. Critical control characteristics are those characteristics of a product or process either designated by the customer or selected by QE through knowledge of the product or process. They are important and need to be controlled with special attention as excessive variation may affect product safety, compliance with government regulations, fit, function, or quality of subsequent operations.
Supplier Responsibilities:
1 Suppliers, if instructed by DENSO, shall use the definitions and symbols regulated by DENSO (see Table 4). Suppliers shall indicate critical control designation in the manufacturing process and on the related documentation such as drawings, PFMEAs, control plans, job instructions, inspection standards, data sheets, **[MAQMSR]:** including adherence to the following: a) measurement techniques. b) sampling plans. c) acceptance criteria. d) records of actual measurement values and/or test results for variable data. e) reaction plans and escalation process when acceptance criteria are not met. **NOTE:** Significant process events, such as tool change or machine repair, shall be recorded and retained as documented information. The supplier shall maintain records of effective dates of process changes. Suppliers of parts and materials with critical control characteristic symbols are required to maintain on-going process capability and process performance monitoring on these products. DENSO requirements for short term capability and performance should follow tables 1a and 1b, and long term capability and performance should follow tables 2a, 2b, 2c and 2d unless otherwise approved by your DENSO Quality Representative. Upon request (typically on an annual basis) suppliers will be required to confirm process capability (Cp, Cpk) and performance (Pp, Ppk) by completing and submitting a process self-assessment sheet. DENSO Quality Representatives will also conduct on-site reviews (typically once per three years) to confirm supplier process capability. In addition to DENSO identified critical control characteristics, suppliers are also required to confirm compliance to DENSO customer “Special Process” requirements. These processes included, but are not limited to heat treating, plating, coating, welding, soldering, and molding. Suppliers are responsible to provide evidence (on an annual basis) showing each process was assessed and conforms to the applicable CQI standard. In the case of process non-conformities, suppliers are expected to implement corrective action to bring the process to compliance. DENSO suppliers must confirm lower tier supplier compliance to the full scope of special process requirements. DENSO will notify suppliers that critical control characteristics are applicable by releasing a drawing or specification with critical control symbols and by issuing a Notice of Quality Assurance Requirements (NQAR) or a Supplier Shipping Inspection Standard. Suppliers must conduct initial process capability (Cp,Cpk) and/or process performance studies (Pp,Ppk) for each designated characteristic in order to obtain information on the variation in a process (see Reference Table 1a and 1b).

Capability studies measure the inherent variation within subgroups (see Reference Figure 1) that exists in a process that is under statistical control. These process capability studies are only for within subgroup variation and will not predict the effects of time and variation in people, materials, equipment, measurement system and environment. Therefore, process performance studies (Pp, Ppk) are recommended which measure the variation of the whole sample (see Reference Figure 1). This variation includes variation between subgroups such as: variation in people, material, etc. over time. The goal is to reduce the spread of variation to less than the tolerances stated within the product specification with some safety margin. Long term process capability and process performance studies should be made available at DENSO's request (see Reference Table 2a, 2b, 2c & 2d).

Figure 1: Population, Sample and Sub-group



Note: *Mass production long term capability and performance studies must include all sources of variation (e.g. shifts, die set, material source, etc.).*

1. Capability and performance studies can be affected by engineering changes and process changes. Therefore, they must be re-submitted for characteristics affected by these changes as required by the DENSO process/engineering change system.

Table 1a: Initial Process Capability and Performance Study Requirements: **Critical Control Characteristics**

Requirement	Explanation
	Critical Control Characteristics
Number of Samples	As defined by DENSO Quality Representative
Expectations: 1) Process	Must be statistically in control (***Note***[1])
2) Process	Follows a normal distribution around the mean value (***Note***[1])
3) Cpk and/or Ppk	1.67 or greater (***Note***[2])
If expectation is not achieved:	Provide Countermeasure and inspection plan to DENSO Quality Representative for approval (***Note***[4])

Table 1b: Initial Process Capability and performance Study Requirements: **Non Critical Characteristics**

Requirement	Explanation
	Non Critical Characteristics

Number of Samples	As defined by DENSO Quality Representative
Expectations: 1) Process	Must be statistically in control (***Note***[1])
2) Process	Follows a normal distribution around the mean value (***Note***[1])
3) Cpk and/or Ppk	1.33 or greater (***Note***[2])
If expectation is not achieved:	Provide Countermeasure and inspection plan to DENSO Quality Representative for approval (***Note***[4])

Note [1] *Critical Control Items require the use of appropriate statistical control techniques. Refer to the AIAG manual Statistical Process Control- SPC for appropriate examples of statistical controls. A process is considered "Normally distributed" when the probability plot has a "P-value" of .05 or greater on a probability plot.*

Note [2] Requirement for Cpk, Ppk, or both will be made based upon customer requirement.

Table 2a: Long Term Process Capability Requirements: **Critical Control Characteristics**

	Actions on the process output (based on the historical process capability (**Cpk**)		
	Critical Control Characteristics		
The most recent point indicates that the process (see below):	Less than 1.33	1.33 - 1.67	Greater than 1.67
Is in control and follows a normal distribution (***Note***[3])	Contact DENSO Quality Representative to discuss appropriate countermeasure.	Accept product. Continue to reduce process variation. Pursue Cpk of 1.67 or greater.	Accept product. Continue to reduce process variation.
Is in control and does not follow a normal distribution	Perform data transformation, or contact DENSO Quality Representative for assistance.	Perform data transformation, or contact DENSO Quality Representative for assistance.	Perform data transformation, or contact DENSO Quality Representative for assistance.
Has gone out of control in an adverse direction. All individuals in the sample are within specification (***Note***[3])	Contact DENSO Quality Representative to discuss appropriate countermeasure.	a). Perform sampling (***Note***[4]) on existing product, construct histogram from those samples, and take appropriate action. b) Increase sampling frequency until stability is re-established.	Accept product. Continue to reduce process variation.
Has gone out of control and one or more individuals in the sample are outside specification (***Note***[3])	Inspect 100% since the last in-control point. Use average and range charts (X, R).	N.A.	N.A.

Table 2b: Long Term Process Performance Requirements: **Critical Control Characteristics**

	Actions on the process output (based on the historical process Performance (**Ppk**))		
	Critical Control Characteristics		
The most recent point indicates that the process (see below):	Less than 1.33	1.33 - 1.67	Greater than 1.67

Is in control and follows a normal distribution (***Note[3]***)	Contact DENSO Quality Representative to discuss appropriate countermeasure.	Accept product. Continue to reduce process variation. Pursue Ppk of 1.67 or greater.	Accept product. Continue to reduce process variation.
Is in control and does not follow a normal distribution	Perform data transformation, or contact DENSO Quality Representative for assistance.	Perform data transformation, or contact DENSO Quality Representative for assistance.	Perform data transformation, or contact DENSO Quality Representative for assistance.
Has gone out of control in an adverse direction. All individuals in the sample are within specification (***Note[3]***)	Contact DENSO Quality Representative to discuss appropriate countermeasure.	a). Perform sampling (***Note[4]***) on existing product, construct histogram from those samples, and take appropriate action. b) Increase sampling frequency until stability is re-established.	Accept product. Continue to reduce process variation.
Has gone out of control and one or more individuals in the sample are outside specification (***Note[3]***)	Inspect 100% since the last in-control point. Use average and range charts (X, R).	N.A.	N.A.

Table 2c: Long Term Process Capability Requirements: **Non Critical Characteristics**

	Actions on the process output (based on the historical process capability (**Cpk**))	
	Non Critical Characteristics	
The most recent point indicates that the process (see below):	Less than 1.00	Greater than 1.00
Is in control and follows a normal distribution (***Note[3]***)	Contact DENSO Quality Representative to discuss appropriate countermeasure.	Accept product. Continue to reduce process variation. Pursue Cpk of 1.33 or greater.
Is in control and does not follow a normal distribution	Perform data transformation, or contact DENSO Quality Representative for assistance.	Perform data transformation, or contact DENSO Quality Representative for assistance.
Has gone out of control in an adverse direction. All individuals in the sample are within specification (***Note[3]***)	Contact DENSO Quality Representative to discuss appropriate countermeasure.	a). Perform sampling (***Note[4]***) on existing product, construct histogram from those samples, and take appropriate action. b) Increase sampling frequency until stability is re-established.
Has gone out of control and one or more individuals in the sample are outside specification (***Note[3]***)	Inspect 100% since the last in-control point. Use average and range charts (X, R).	N.A.

Table 2d: Long Term Process Performance Requirements: **Non Critical Characteristics**

	Actions on the process output (based on the historical process performance (**Ppk**))

	Non Critical Characteristics	
The most recent point indicates that the process (see below):	Less than 1.00	Greater than 1.00
Is in control and follows a normal distribution (***Note***[3])	Contact DENSO Quality Representative to discuss appropriate countermeasure.	Accept product. Continue to reduce process variation. Pursue Ppk of 1.33 or greater.
Is in control and does not follow a normal distribution	Perform data transformation, or contact DENSO Quality Representative for assistance.	Perform data transformation, or contact DENSO Quality Representative for assistance.
Has gone out of control in an adverse direction. All individuals in the sample are within specification (***Note***[3])	Contact DENSO Quality Representative to discuss appropriate countermeasure.	a). Perform sampling (***Note***[4]) on existing product, construct histogram from those samples, and take appropriate action. b) Increase sampling frequency until stability is re-established.
Has gone out of control and one or more individuals in the sample are outside specification (***Note***[3])	Inspect 100% since the last in-control point. Use average and range charts (X, R).	N.A.

Note [3] *Control refers to the status of process stability. An "out of control" condition is defined by evidence of special causes of variation on the Statistical Process Control Charts (SPC) with control limits defined from the data. A process is considered "in control" when no evidence of special causes is found. The "8 special cause tests" can be used to identify if a process is "in control".*

Note [4] *See Table 3 for the acceptable sample size.*

Table 3: Sampling Quantity Determination

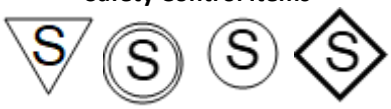
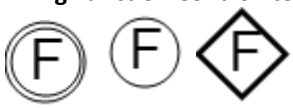
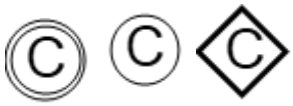
(Note: This table is only an example; it can be different per product and shall be specified by your DENSO Quality *Representative)*

Lot size or shipment size	Sample quantity per characteristic (Classification acceptance number = 0)(***Note***[5])
0 - 25	All
26 - 50	25
51 - 75	35
76 – 125	40
126 - 425	45
426 and up	50

Note [5] *If one or more individuals in the sample are out of specification, inspect 100% since last in-control point.*

Table 4: critical control characteristics symbols & criteria

No.	Category	Description

1	**Safety Control Items** 	Products, parts, components and materials which could lead to injuries, death, car fire and/or other accidents of grave consequence if they are defective, fail, or are improperly handled.
2	**Emission Control Items** 	Products, parts, components and materials whose defect or failure could lead to an impediment of the exhaust gas purification system and of sensing or alarm indication features and other emission-related functions.
3	**Running Function Control Items** 	Products, parts, components and materials whose defect or failure could lead to an impediment of the running function of the automobile into which they are assembled.
4	**Critical Control Items** 	Products, parts, components and materials which could bring about any impediment of significance, other than those mentioned above, as a consequence of their defect or failure.
5	**Customer Mount Items** 	Processes where the manufacturing point of origin creates a Customer end-use mounting feature and is the only source of prevention and/ or detection (excluding QC-FI) for such a feature. 100% verification is required.
6	**Special Process** 	Process where production (products) defects are difficult to identify. (1) Soldering; (2) Heat Treatment; (3) Plating; (4) Welding / Fusing; (5) Molding for electric circuit insulation; (6) Related section agreement process based on past problem history (7) Rubber. (100% verification only applicable to assigned critical characteristics)
7	**Installation Control** 	(In) = Installation: Contact portion that occurs when DENSO products are installed in the vehicle and products (engine, transmission, body) by customer, or mating parts (connector, pipe) and equipment are installed in DENSO products. 100% guarantee (CPK of 1.67 should be achieved and a Quality check at a frequency to ensure no flow out. If CPK is less than 1.67 the Quality check should occur @ 100% to ensure no flow out) required.
8	**Regulation Control Items** 	Product which a responsible General Manager of Eng. Dept. decides necessary for the designation when considering prevention for lack of certification marks and for incompatibility with legal regulations against products except Designation Types S and E.
9		Products, parts, components and materials which if one dimensions is NG avoid the correct assembly into the car (This symbol is unique to DNMX-KINHOUIN Plant).

Note [6]*: Diamond designations are applied to products having a direct effect on Safety, Emission, and/or Running Function Items. Circle designations have an indirect effect on the product designation and are not as critical as the diamond designations.*

DENSO critical symbol definitions;

◇*Result-Related Characteristics require 100% verification (if possible).*

(Can be characteristic or function).

○ *Factor-Related Characteristics require sampling inspection, (Can be product or process or function characteristics).*

◎ *Factor-Related Characteristics require 100% verification, can be product or process characteristics linked to ◇ characteristics. (Example: furnace temperature as a process characteristic)*

▽ *Customer's Designation Characteristics require 100% verification (if possible), (Can be product or process or function characteristics).*

Note [7]*: Drawings may also include customer related symbols that are not indicated above, please contact lease contact your QA/QC representative if you have any questions.*

II.d PFMEA

TOC

Purpose:
The purpose of this section will explain PFMEA requirements to DENSO suppliers.
Scope:
PFMEA requirements apply to suppliers of production parts and raw materials. DENSO will identify application of AIAG 4th Edition FMEA or AIAG-VDA FMEA Handbook Methods.
Link to ISO / MAQMSR:
6.1.2.1 Risk Analysis / 6.1.2.2 Preventive action / 10.2.4 Error proofing
Documents related:
N/A

Explanation:

PFMEA ensures all process failure modes and outputs are controlled at known risk levels. Effective process control relies on the output of effective PFMEA's.

The PFMEA ensures process step requirements and expectations are analyzed to understand process output risk levels.

Inputs to PFMEA include DENSO Statement of Requirements, NQAR, product specification requirements, lessons learned, past problems, process capability considerations, **[MAQMSR]:** lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework, etc. DENSO QE will provide information to:

1. Inform the supplier whether their part is exempt from specific PFMEA criteria and rules below.
2. Support critical control item evaluation.
3. Harmonize applicable supplier process failure effects with DENSO product failure effects.
4. S - D (Severity-Detection) analysis; shall be completed but if questions exist by the supplier, please reach out to your DENSO SQE for guidance.

Supplier Responsibilities:

[**MAQMSR**]: The supplier shall determine and implement action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the severity of potential issues.

The supplier shall establish a process to lessen the impact of negative effects of risk including the following:

1. Determining potential nonconformities and their causes.
2. Evaluating the need for action to prevent occurrence of nonconformities.
3. Determining and implementing action needed.
4. Documented information of action taken.
5. Reviewing the effectiveness of the preventive action taken.
6. Utilizing lessons learned to prevent recurrence in similar processes.
7. Production operations producing DENSO product are analyzed using the PFMEA.
8. Supplier assures PFMEA risk levels (RPN or AP) are produced from consistent application of Severity, Occurrence, and Detection criteria traceable to applicable AIAG FMEA risk rank tables.
9. FMEA Methods; new production lines and new process additions must apply AIAG & VDA FMEA methods. **(4th Edition AIAG FMEA)**; Activation of risk reduction by only RPN Threshold is not accepted practice. Supplier management will review all S=8 and S=9 and S=10 and RPN > 130 situations. The supplier must pursue risk reduction for all RPN's > 130. Supplier will explain risk reduction, remaining risks, and PCP content to manage risks. Additional risk management is explained below.

   NOTE: (AIAG-VDA FMEA Handbook); Supplier management will review all S=8 and S=9 and S=10 and AP=H situations and show evidence of review and risk reduction efforts. All AP=M are reviewed for risk reduction opportunities. Supplier will explain risk reduction, remaining risks, and PCP content to manage risk.
10. PFMEA functions + requirements, causes and controls become inputs for the PCP.
11. PFC-PFMEA-PCP-Work Instruction-Checklists-Training should have content linkage.
12. PFMEA evaluation is expected before process change requests.

13. Periodic PFMEA re-evaluation and updates are expected. Periodic High Risk item reviews include risk reduction progress, risk changes, and confirmation Occurrence levels do not exceed PPAP levels.
14. PFMEA document submission with PPAP documentation is determined with DENSO agreement.
15. In the case of process changes involving S>7 requirements, high severity Risk Management must be applied.
16. In the case of high severity (S>7 & D>4) poor quality outflow to DENSO, application of Risk Management is applied. This rule also applies to processes approved prior to introduction of Risk Management (below).

Supplier Responsibility, Process Design

1. Supplier will review PFMEA with DENSO QE as soon as possible, review early before process design finalization when changes are less expensive and not constrained by scheduling.
2. Examine Severity and Detection Rank for each output requirement/expectation.
3. All high Severity Ranks (S>7) must see D<5 (method to avoid human check inspection, identifies machine/tool/pokayoke based detection). All medium Severity Ranks (Severity of 5 through 7) should have a Detection of 1 to 6.
4. Record correlating S-D occurrences (for each requirement) in a PFMEA Severity Matrix.
5. S-D should fall in Green Zone for each process output requirement & expectation.
6. Evaluate failure modes, improve detection of failure modes and/or failure causes to reduce Process Step Risk Rank.
7. S-D Occurrences in the red zone must receive improvement. If risk reduction into yellow or green zones is not immediately possible, Zone Controls (secondary layer of protection) are added. Zone controls are included in the PFMEA (as actions taken) and carried into the PCP.
8. S-D Occurrences in the yellow zone must receive improvement consideration.
9. Primary Controls and Zone controls (from remaining high risk) must be audited at least once per shift to confirm proper execution of controls.
10. Collaborate with DENSO QE, improvement ideas may be available.

- (see PFMEA Severity matrix example below).

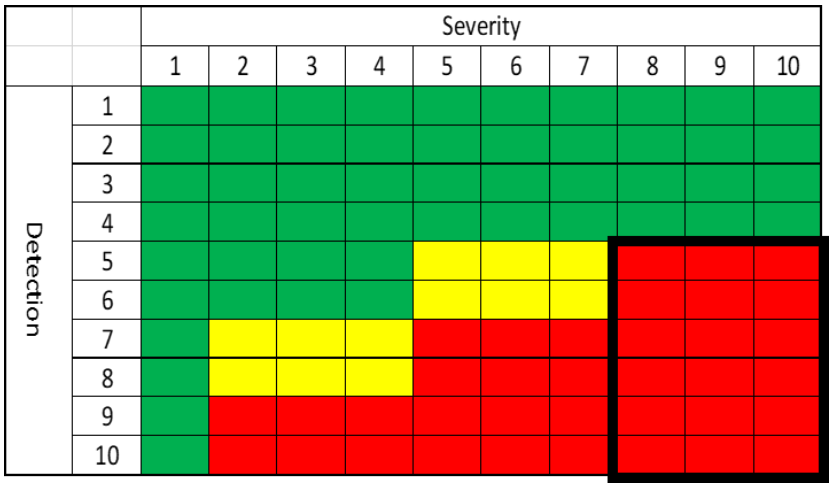
Example

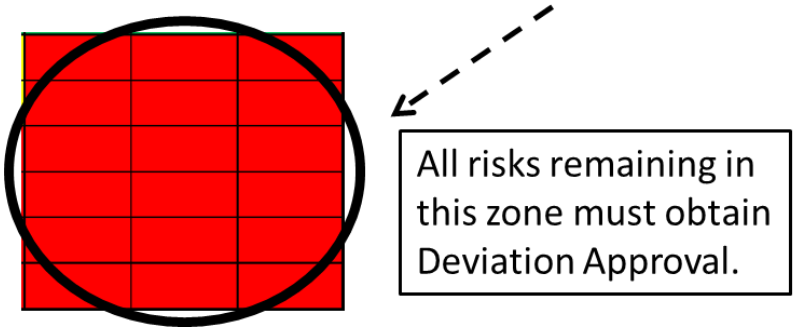
PFMEA Detection		PFMEA SEVERITY									
			C Rank Target Zone			B Rank Target Zone			A Rank Target Zone		
		1	2	3	4	5	6	7	8	9	10
A Rank MC Controls	1	1	0	0	17	6	19	0	0	92	0
	2	0	0	0	0	0	0	0	0	0	0
	3	0	0	4	12	21	23	0	0	56	0
	4	0	0	0	14	16	45	0	0	73	1
B / C Rank MC & Human Controls	5	0	0	0	0	0	0	0	0	0	0
	6	0	0	0	0	0	0	0	0	0	0
(C) & D Rank Human Controls	7	0	0	0	0	0	0	0	0	0	0
	8	1	6	4	210	18	13	0	0	1	0
	9	0	0	0	0	0	0	0	0	0	0
	10	0	0	0	0	0	0	0	0	0	0

LOW	MED	HIGH	TOTAL
321	220	32	573

Process Reliability
94%

$$\% = \frac{321 + 220}{573}$$





***Supplier Responsibility, Process Performance*.**

1. Evaluate failure causes, improve prevention controls to reduce Occurrence Rank.
2. Evaluate failure causes, improve detection of causes or failures to reduce Detection Control Rank.

Risk Management if target risk reduction is not possible.

1. Supplier Mgmt must review risks exceeding DENSO Standards (Red zone in SD chart and RPN or AP exceeding thresholds in Supplier Responsibility, element # 3).
2. Supplier Management must submit a PFMEA deviation request for Red Zone items in S>7 and D>4. Process Output Requirement(s), failure modes – causes – controls are identified. Risk reduction limitation is explained. Short and long term risk reduction plans are explained.

[MAQMSR]: Error proofing

The supplier shall have a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used shall be documented in the process risk analysis (such as PFMEA) and test frequencies shall be documented in the control plan. The process shall include the testing of error-proofing devices for failure or simulated failure. Records shall be maintained. Challenge parts, when used, shall be identified controlled, verified, and calibrated where feasible. Error-proofing device failures shall have a reaction plan.

II.e QA Network

TOC

Purpose:
The system is used to foresee potential defects, to understand process QA weak spots, and take proactive QA Net strengthening countermeasures considering the full production process from sub-suppliers to shipping product.
Scope:
This section applies to suppliers of production parts and raw materials to DENSO when specified by your DENSO Quality Representative. QA Network analysis may be required for new parts and materials supplied to DENSO. The QA Network is a 'living document' and should be updated accordingly when the process is modified or new defect modes are discovered.
Link to ISO / MAQMSR:
N/A (DENSO unique requirement)
Documents related:
QA Network Evaluation Form

Explanation:
DENSO's QA Network is a matrix tool in which critical assurance items are identified and ranked according to occurrence and flow-out possibility. The purpose is to foresee potential defects for proactive control improvements.
Supplier Responsibilities:
1. The supplier is responsible to list and consider all part critical items provided by DENSO along with other important or critical items, which are understood, based on the process design, PFMEA, or 'know-how' of the supplier. 2. The supplier is responsible to coordinate the QA Network information from sub-supplier [i.e. material or sub-assembly process] and sub-contracted process [i.e. plating or heat treating] considering the full supply chain. 3. The supplier is responsible to take appropriate action to improve any weak areas identified through the QA Network ranking system. After mass production, the supplier is responsible to maintain and revise the QA Network worksheet as required and resubmit the updated worksheet to DENSO.

II.f MSA

TOC

Purpose:
The purpose of this section will be to explain Measurement Systems Analysis (MSA) requirements to DENSO suppliers. This section applies to suppliers of production parts and raw materials.
Scope:
This section applies to suppliers of production parts and raw materials.
Link to ISO / MAQMSR:
7.1.5.1.1 Measuring System Analysis / 7.1.5.2 Measurement Traceability / 7.1.5.2.1 Calibration-Verification Records
Documents related:
N/A

Explanation:
Measurement systems are used to monitor conformity of products to DENSO requirements. MSA methods verify process outputs can be measured with a high probability of correct values.
Supplier Responsibilities:
The supplier shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. The supplier shall ensure that the resources provided: 1. Are suitable for the specific type of monitoring and measurement activities being undertaken; 2. Are maintained to ensure their continuing fitness for their purpose. 3. Production quality control measurement systems are calibrated and verified at specified intervals. 4. Measurement systems supporting operations producing DENSO products are managed using MSA methods. Statistical studies should be performed to analyze measurement system variation (see current AIAG MSA Manual) 5. Supplier will produce gauge instructions as needed to assure effective use of measurement systems. 6. Countermeasures for unacceptable measurement system variation are required and included in the PCP. Supplier will explain excess variation and excess variation countermeasures. 7. The supplier maintains documented information showing evidence of measurement systems fitness for purpose. **[MAQMSR]:** NOTE: Other analytical methods and acceptance criteria may be used if approved by DENSO. Records of DENSO acceptance of alternative methods shall be retained along with results from alternative measurement systems analysis. NOTE: Prioritization of MSA studies should focus on critical or special product or process characteristics. **[ISO]: Measurement Traceability** When measurement traceability is a requirement, or is considered by the supplier to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information. b) identified in order to determine their status. c) safe guarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. The supplier shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary. **[MAQMSR]: Calibration / Verification Records** The supplier shall have a documented process for managing calibration/verification records. Records of the calibration/verification activity for all gauges and measuring and test equipment (including employee-owned equipment relevant for measuring, customer-owned equipment, or on-site supplier-owned equipment) needed to

provide evidence of conformity to internal requirements, legislative and regulatory requirements, and customer-defined requirements shall be retained.
The supplier shall ensure that calibration/verification activities and records shall include the following details:
a) revisions following engineering changes that impact measurement systems.
b) any out-of-specification readings as received for calibration/verification.
c) an assessment of the risk of the intended use of the product caused by out-of-specification condition.
d) when a piece of inspection measurement and test equipment is found to be out of calibration or defective during its planned verification or calibration or during its use, documented information on the validity of previous measurement results obtained with this piece of inspection measurement and test equipment shall be retained, including the associated standard's last calibration date and the next due date on the calibration report.
e) notification to the customer if suspect product or material has been shipped.
f) statements of conformity to specification after calibration/verification.
g) verification that the software version used for product and process control is as specified.
h) records of the calibration and maintenance activities for all gauging (including employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment).
i) production-related software verification used for product and process control (including software installed on employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment).

II.g Control Plans

TOC

Purpose:
The purpose of this section is to explain the control plans submission and requirements to DENSO suppliers.
Scope:
This section applies to suppliers of production parts and raw materials specified on the Notification of Quality Assurance Requirements (NQAR).
Link to ISO / MAQMSR:
8.5.1.1 Control Plan / 8.5.1.2 Standardized work – operator instructions and visual standards / 8.5.1.3 Verification job set-ups / 8.5.1.4 Verification after shutdown / 8.5.1.5 Total Productive Maintenance / Annex A
Documents related:
N/A

Explanation:

The objective of the control plans is to ensure that all process outputs will be in control by providing process monitoring and control methods to manage the associated product and process characteristics. Process control relies upon control of the elements that drive the process, whereas product control verification of the product as it emerges from the process. In practice it is a combination of these that yields products of consistent quality.
The control plans include critical product characteristics, all process steps, all quality assurance check items, and their frequency, SPC reporting method, process capability, and Gage R & R (Reference manuals AIAG "Measurement Systems Analysis - MSA" and "Statistical Process Control - SPC" for general explanations of Gage R&R and SPC systems). AIAG manuals: order at: https://www.aiag.org/quality/automotive-core-tools

[MAQMSR]: See the following table for control plan guidelines:

Section	Details
1. Phases of the control Plan	A control plan covers three distinct phases, as appropriate: a) Prototype: a description of the dimensional measurements, material, and performance tests that will occur during building of the prototype. The organization shall have a prototype control plan, if required by the customer. b) Pre-launch: a description of the dimensional measurements, material, and performance tests that occur after prototype and before full production. Pre-launch is defined as production phase in the process of product realization that may be required after prototype build. c) Production: documentation of the product/process characteristics, process controls, tests, and measurement systems that occur during mass production. Control plans are established at a part number level; but in many cases, family control plans may cover a number of similar parts produced using a common process. Control plans are an output of the quality plan. NOTE 1 It is recommended that the organization require its suppliers to meet the requirements of this Annex. NOTE 2 For some bulk materials, the control plans do not list most of the production information. This information can be found in the corresponding batch formulations/recipe details.

2. Elements of the control plan	A control plan includes, as a minimum, the following contents: **General data** a) control plan number; b) issue date and revision date, if any; c) customer information (see customer requirements); d) organization's name/site designation; e) part number(s); f) part name/description; g) engineering change level; h) phase covered (prototype, pre-launce, production); i) key contact; j) part/process step number; k) process name/operation description; l) functional group/are responsible. **Product control** a) product-related special characteristics; b) other characteristics for control (number, product or process); c) specification/tolerance. **Process control** a) process parameters (including process settings and tolerances); b) process-related special characteristics; c) machines, jigs, fixtures, tools for manufacturing (including identifiers, as appropriate). **Methods** a) evaluation measurement technique; b) error-proofing; c) sample size and frequency; d) control method. **Reaction plan** a) reaction plan (include or reference).

Supplier Responsibilities:

1. Control Plan

a) The control plan is to be written, controlled, and submitted by the supplier's quality section (QA Representative), and submitted to DENSO Quality Representative. The control plan content must meet all the requirements outlined in the IATF 16949, AIAG manual "Advanced Product Quality Planning and Control Plan- APQP". The format is optional, but the AIAG format is recommended. The Control Plan the supplier uses must include all critical items from Receiving Inspection through Packaging.

b) Submission timing is in accordance with NQAR (Reference Section II.a – NQAR).

c) Suppliers must test and analyze the process to obtain results that support the Control Plan contents.

d) For raw materials, the detailed specifications and evaluation methods should be noted on the control plan.

e) The control plan must be approved by the supplier's chain of command.

f) Control plan revisions related to a process change must be issued to DENSO. Your QE representative may request a control plan revision as deemed necessary.

g) Revisions must be reviewed by DENSO prior to shipment of parts reflecting the change. Depending on the change, other submittals may be required.

h) No process change, temporary or permanent, is allowed after the start of mass production unless a process change request sheet has been submitted and approved by DENSO (Reference Section III.d - Process and Design Change Request (PCR).

i) Check items requiring conformance to standard test methods (ISO, DIN, JIS, etc.) should be indicated.

j) On-going Conformance requirements, as requested and/or agreed with your respective Denso QE, should be indicated within the Control Plan.

[MAQMSR]2. Standardized work – operator instructions and visual standards
The supplier shall ensure that standardized work documents are:
a) communicated to and understood by the employees who are responsible for performing the work
b) legible
c) presented in the language(s) understood by the personnel responsible to follow them
d) accessible for use at the designated work area(s)
The standardized work documents shall also include rules for operator safety.

[MAQMSR] 3. Verification of job set-ups
The supplier shall:
a) verify job set-ups when performed, such as an initial run of a job, material changeover, or job change that requires a new set-up.
b) maintain documented information 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; where appropriate, last-off-parts should be retained for comparison with first-off parts in subsequent runs.
e) retain records of process and product approval following set-up and first-off/last-off part validations.
NOTE: The supplier shall define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.

[MAQMSR] 4. Total Productive maintenance
The supplier shall develop, implement, and maintain a documented total productive maintenance system. At a minimum, the system shall include the following:
a) identification of process equipment necessary to produce 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 maintenance objectives, for example: OEE (Overall Equipment Effectiveness), MTBF (Mean Time Between Failure), and MTTR (Mean Time To Repair), and Preventive Maintenance compliance metrics. Performance to the maintenance objectives shall form an input into management review.
g) regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved.
h) use of preventive maintenance methods.
i) use of predictive maintenance methods, as applicable.
j) periodic overhaul.

II.h PPAP Initial Sample Submission

TOC

Purpose:
The purpose of this section describes supplier requirements for submission of part and/or material data along with samples (if required) for PPAP evaluation. The parts, materials, and/or data are to meet DENSO drawings and specifications.
Scope:
This section applies to suppliers of production parts and raw materials for products produced for initial sample inspection for PPAP evaluation.
Link to ISO / MAQMSR:
8.3.4.4 Product Approval Process
Documents related:
ISIR Form

Explanation:
1. Initial samples and data for new parts and materials shall be delivered to your DENSO Quality Representative by the specified due date. 2. The DENSO Quality Representative will communicate the sample requirements to the supplier contact. Samples should be off mass production tooling, process, and intended production location, unless otherwise approved by DENSO. 3. The supplier shall tag or mark the sample product as instructed by your DENSO Quality Representative and package/label the shipment as instructed to the attention of your DENSO Quality Representative. Required documentation shall be included in the sample product. (i.e., ISIR or Shipping Inspection Standard).
Supplier Responsibilities:
[MAQMSR] 1. The supplier shall establish, implement, and maintain a product and manufacturing approval process conforming to requirements defined by DENSO. The supplier shall approve externally provided products and services per ISO 9001, Section 8.4.3 Information for external providers, prior to submission of their part approval to DENSO. The supplier shall obtain documented product approval prior to shipment, if required by DENSO. Records of such approval shall be retained. **NOTE** Product approval should be subsequent to the verification of the manufacturing process. 2. Part Submission Requirements – (Unless otherwise instructed by your DENSO Quality Representative) A) Balloon the drawing and dimensions (using reference numbers). B) Number each dimension sequentially. C) Measure all drawing or material specification items including all notes, dimensions, special tests, and record on the specified format (e.g. ISIR or sample data sheet). D) All dimensions shall be measured, unless otherwise specified. It is the supplier's responsibility to measure every dimension or material test item. If the supplier does not have measurement or testing capability, they must contact their DENSO Quality representative for guidance. E) The supplier shall submit the requested documentation with trial submission. If one or more dimensions do not meet specifications complete the required deviation approval request forms as instructed by your DENSO Quality Representative. F) All cavities and dies must be included in dimensional sheets unless otherwise directed by your Quality Representative. Two parts per cavity should be measured and reported in the initial sample inspection report unless otherwise directed. G) The supplier shall retain initial samples from PPAP submission timing. 3. Material Submission Requirements A) For all materials submitted to DENSO, the supplier is required to record the Material Test data on the ISIR Report or other format specified by your DENSO Quality Representative.

B) Supply the required number of test specimens or material. A material certification and test report may be used in place of the ISIR or Trial Submission Warrant, as communicated by your DENSO Quality Representative.
C) Resubmission of materials samples will be communicated to you by your DENSO Quality Representative. Examples of resubmission request may include process changes, re-start of production after extended non-supply, etc.

II.i Lot Identification and Traceability

TOC

Purpose:
The purpose of this section is to define supplier requirements for lot identification and traceability of parts and materials.
Scope:
This section applies to suppliers of production parts and raw materials. Lot identification and traceability requirements extend to sub-suppliers.
Link to ISO / MAQMSR:
8.5.2, 8.5.2.1 Identification and traceability
Documents related:
Lot identification and traceability

Explanation:

1. Definition of lot

The lot refers to a group of materials, parts, and products that are manufactured under the same conditions (date, operator, equipment, manufacturing condition, raw material, etc.). Typical lot size/qty and lot process should be identified by the supplier.

2. Traceability

The term traceability refers to the ability to track a part back through all stages of manufacture to raw materials. Some examples of traceability that DENSO is looking for are:

a) Lot number and size.
b) Production location, date, line, and shift.
c) Rework, rejects and scrap.

Supplier and lower tiers should consider adding these items to their traceability system:

a) Sub-component receipt and associated utilization dates.
b) Process parameters, maintenance history, and machine calibration.
c) Manpower changes and training.
d) Finished goods ship dates and destinations.
e) ECI and process changes.

Process parameters used in manufacture of critical components should also be traceable, with applicable inspection and test results.

The supplier is responsible for defining and tracking items needed for proper traceability based on their knowledge and understanding of their product and process.

3. Identification

The term identification refers to the method a supplier uses to identify a part in the event a problem occurs. This is important in that it allows the necessary information to be quickly collected should the need arise within the product pipeline (sub-suppliers through end customer). This typically includes:

a) Part number
b) Special identification marks (material type, inspection item, etc.)
c) Date of Manufacture, Packaging or Shipping (supplier must clearly indicate which of these applies)
d) Cavity or mold number(s)
e) Lot Numbers that should be noted on all supplied materials documents, such as:
    a. Material Specification Documents
    b. Material Test Reports
    c. Materials Packaging

d. Any other documents or packaging related to a specific lot of material

With the above information, the supplier should be able to accurately determine the lot size, in process stock, final inventory at the supplier and the in-transit quantity of parts/material with the applicable dates. Therefore, if the supplier is notified by the DENSO Quality Representative of a non-conformance or other need, the supplier will be able to use this information to take containment and/or other actions as necessary. Traceability records must be retained and accessible to define the non-conforming product range from sub-supplier to end customer and vice versa.

Supplier Responsibilities:

1. Traceability

a. All parts must have a traceability system that consists of a clear start and stop point for each lot. The supplier must ensure that documented systems are in place at all sub-suppliers to control lot identification and traceability of all components using the list of items above in Sections II.i.2 (Traceability) and II.i.3 (Identification).

b. When requested by DENSO, the supplier must list the components, materials, and /or processes that are traced and traceable using the final lot number designation on the Lot Traceability Information Sheet, including a sample or sketch of the lot control tag.

c. If the part/material supplied has a shelf life (expiration date), it must be recorded on the Lot Traceability Information Sheet and clearly identifiable on the associated product shipping labels.

d. Traceability Methods that can be utilized:
i. Lot Traceability – specific amount of materials, sub-components, are contained within a production size or volume (production shift, production dates and/or time range, quantity produced, etc.)
ii. Serial Number Traceability – unique code assigned to permanently identify a part by using a serial number label or serial number direct part marking such as laser etching.

2. Identification

a. All products must be clearly identified per drawing or specification requirements. Some examples that should be considered are right hand – left hand identification, label code, production location, and month-date dial. Various options to apply identification marks could be alpha-numeric labeling or direct part marking. The supplier must clearly record the details of the identification method on the Lot Traceability Information Sheet.

b. DENSO will communicate requirements for packaging, labeling, preservation, and shipping.

3. First In First Out (FIFO):

a. To develop and maintain a successful traceability system, a good FIFO system should be utilized.
b. Suppliers should confirm their sub-suppliers' FIFO.
c. Consideration points for good FIFO should be:

i. In-process carts
ii. Materials
iii. Sub-components
iv. Rework and partial lots
v. Raw materials through all production stages until finished goods delivery.

II.j Design and development process

TOC

Purpose:
Design, develop, purchase, install and change process and equipment to meet internal and external requirements.
Scope:
This section applies to suppliers of production parts and raw materials.
Link to ISO / MAQMSR:
8.3, 8.3.1 Design and development of products and services / 8.3.2 Design and development planning / 8.3.3 Design and development inputs / 8.3.4 Design and development controls / 8.3.5 Design and development outputs / 8.3.6 Design and development changes.
Documents related:
N/A

Explanation:
[ISO]: The supplier shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.
Supplier Responsibilities:
[ISO]: Design and development Planning In determining the stages and controls for design and development, the supplier shall consider: 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 activities. 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 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 documented information needed to demonstrate that design and development requirements have been met. **[ISO]: Design and development Inputs** The supplier shall determine the requirements essential for the specific types of products and services to be designed and developed. The supplier shall consider: 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 the organization has committed to implement. e) potential consequences of failure due to the nature of the products and services. Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. The supplier shall retain documented information on design and development inputs. **[ISO]: Design and development Controls** The supplier shall apply controls to the design and development process to ensure that: a) the results to be achieved are defined. b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements. 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 and services meet the requirements for the specified application or intended use.
e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities.
f) documented information of these activities is retained.
NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the supplier organization.

[ISO]: Design and development Outputs
The supplier shall ensure that design and development outputs:
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 and services that are essential for their intended purpose and their safe and proper provision.
The supplier shall retain documented information on design and development outputs.

[ISO]: Design and development Changes
The supplier shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.
The supplier shall retain documented information on:
a) design and development changes.
b) the results of reviews.
c) the authorization of the changes.
d) the actions taken to prevent adverse impacts.

II.k Early Stage Control (ESC) for Mass Production Ramp-Up

TOC

Purpose:
The purpose of this section is to outline the supplier quality assurance activities during volume ramp-up to mass production.
Scope:
This section applies to suppliers of production parts and raw materials to DENSO when specified by your DENSO Quality Representative.
Link to ISO / MAQMSR:
8.6 Release of products and services.
Documents related:
ESC Forms

Explanation:
During the initial Mass Production ramp-up, the supplier must undertake activities to ensure that quality and process standards are adhered to until the process becomes stable. The supplier needs to develop and implement an early stage control plan during the ramp-up period. This plan covers items found on the standard control plan, though required inspection rates may be higher during early stage. In addition, it can include other items that are critical for successful implementation of new processes. In some cases, DENSO may dictate items to be checked during early-stage control with associated frequencies.
Supplier Responsibilities:

1. Content of the ESC plan:
    a) Include all control plan items as a minimum.
    b) Suitable goals and targets should focus on defect prevention and quick resolution of production and production control issues that would affect the supplier making shipments to DENSO.
    c) Management review of quality results for initial mass production shipments.
    d) Frequent quality review meetings involving key persons.
    e) The development and implementation of a system for documenting and resolving quality issues and complaints.

2. Timing of submissions for the ESC plan:
    a) The initial submission timing of the ESC plan by the supplier will be communicated by your DENSO Quality Representative.
    b) After the plan is implemented, no earlier than three months after the start of mass production, when process capability is sufficient and there are no specific concerns, the supplier may request approval to stop ESC activities. The request form is fully signed-off by the relevant supplier management and quality representatives and submitted to your DENSO Quality Representative. This sign-off reflects that early controls were enforced and issues encountered were resolved. The supplier should submit supporting data gathered during early stage control, and after DENSO written approval, early stage control can be terminated on the indicated date.

3. During the initial mass production:
The supplier's goal should be to stabilize the process as quickly as possible. During this period (3 months as a standard) no design or major process changes are allowed, with the exception of those required by DENSO.
If quality problems are causing the supplier to miss or not make full shipments, the supplier should contact their DENSO Quality Representative immediately.

II.l Mass Production Readiness Review

TOC

Purpose:
The purpose of this section is to describe the requirements for mass production readiness audits.
Scope:
This section applies to suppliers of production parts and raw materials when deemed necessary by the responsible DENSO division.
Link to ISO / MAQMSR:
8.6 Release of products and services.
Documents related:
Supplier Mass Production Readiness Check sheet

Explanation:
A process review should be conducted by the supplier's management preferably during the last production trial, but before mass production. DENSO may also require an on-site visit to confirm the supplier has completed all activities necessary to ensure a smooth start up of production with a minimal amount of defects / problems and can meet the production volumes.
Supplier Responsibilities:
1. The Supplier should contact their DENSO Quality Representative for information on whether DENSO will perform an on-site production readiness audit and what documentation should be provided ahead of time. 2. Even if DENSO elects not to perform an on-site mass production readiness review, the supplier's management should confirm all activities necessary to ensure a smooth start-up has been completed and that production volumes can be achieved. DENSO may require evidence of this self-audit in associated PPAP or final approval documentation. 3**. [ISO]:** The supplier shall retain documented information on the release of products and services. The documented information shall include evidence of conformity with the acceptance criteria and traceability to the person(s) authorizing the release. 4. When an on-site review is performed, DENSO will issue a report to the supplier summarizing the results of the visit. The report will show results (approved or not approved) and all items requiring countermeasures by the supplier. The supplier is responsible for responding promptly with countermeasures and due dates for all items. Requirements for follow-up activities will be communicated by the DENSO Quality Representative. Note: Failure to respond promptly may result in a delay in receiving Final Approval

II.m Mass Production Approval

TOC

Purpose:
This section describes supplier requirements for obtaining final approval for mass production parts or raw materials.
Scope:
This section applies to suppliers of production parts and raw materials to DENSO.
Link to ISO / MAQMSR:
8.3.4.4 Product Approval Process
Documents related:
N/A

Explanation:

The Final Approval or PPAP process is used by DENSO to confirm that the supplier has demonstrated that production parts or raw materials meet quality requirements. This final approval acknowledges that the supplier's process can consistently provide acceptable quality parts at production volume. A due date for submission is given on the Notification of Quality Assurance Requirements (NQAR), or Supplier Inspection Shipping Standard. Suppliers are encouraged to submit it as soon as all of the required items listed have been completed or considered "N/A" by your DENSO Quality Representative.

Supplier Responsibilities:

1. Supplier shall approve externally provided products and services per ISO 9001, prior to submission of their part approval to DENSO.
2. When all requirements communicated to the supplier have been met, the supplier must submit a Request for Final Approval or Parts Submission Warrant as defined by your DENSO Quality Representative.
3. DENSO will review the supplier's request for Final Approval or Parts Submission Warrant with required PPAP or NQAR documentation and if acceptable, DENSO will approve the request/warrant and return a copy to the supplier.
4. A copy of the Final Approval or Warrant will also be forwarded to DENSO Purchasing to resolve issues involving final (tooling) payment(s).
5. If the Final Approval or Parts Submission Warrant is given a 'conditional approval' or 'rejected', the form will be returned to the supplier along with the reason(s). The supplier must resubmit the Final Approval Request or Parts Submission Warrant with corrections (based on reason(s)) by the due date.

Approval status:

1. Approved

a) Parts including sub components meet all DENSO requirements and the supplier is authorized to ship production quantities.

2. Approved with Special Acceptance/Permanent (die) Deviation:

a) Minor discrepancies exist but are not deemed to be critical to the fit and function of the parts and judged by DENSO to be acceptable for lifetime of production.

3. Approved with Deviation Approval/Temporary Deviation:

a) This means that the dispatch of products is only approved for a certain limited period or a certain number of pieces (deviation approval). The conditions are to be agreed individually between DENSO and supplier.

4. Rejected

a) Part or submission does not meet DENSO requirements, based on the production lot from which it was taken and/or documentation. In such cases the submission and/or process shall be corrected, as appropriate to meet DENSO's requirements. Where product is involved, then its shipment to DENSO is NOT permitted and re-submission is required following corrective action by the supplier.

NOTE: Tooling, equipment and process buy-off shall only occur when the PPAP submission has either full approval or conditional approval with Special Acceptance.

II.n Supplier Capacity Verification

TOC

Purpose:
This section explains DENSO's capacity verification requirements and practices.
Scope:
This section applies to suppliers of production parts and raw materials to DENSO when specified by your DENSO Quality Representative.
Link to ISO / MAQMSR:
8.2.3.1.3 Organization manufacturing feasibility
Documents related:
Capacity Verification Form

Explanation:
It is critical that each supplier is able to produce the target amount of inventory to meet DENSO's volume needs and ensure timely delivery of quality parts to our customers. The Capacity Verification Form (CVF) is one tool to support this effort. Some key information: 1. The CVF may be completed by a DENSO Quality Representative at the Mass Production Readiness visit or at any other visit as required. 2. In some cases, the supplier may be requested to complete the form and supply the completed form to DENSO. 3. Your DENSO quality representative may use the form included in this SQAM or another form of their choice.
Supplier Responsibilities:
1. The supplier will provide necessary information such as the number of shifts, hours, or days/week, as well as downtimes, changeover times, and operation time dedicated to other customers. 2. The supplier should prepare to run the mass production process during the capacity verification step. The length of the run will be specified by the DENSO Quality Representative. 3. If the target capacity is not achieved, the supplier is responsible to develop an improvement plan to achieve target capacity. This plan should be shared with the DENSO Quality Representative for agreement.

II.o Production Quality Evidence

TOC

Purpose:
Define evidence methods to demonstrate evidence of conformity with acceptance criteria.
Scope:
This section applies to suppliers of products and/or services sent to DENSO. (ISO 9001; 8.6)
Link to ISO / MAQMSR:
8.6 Release of products and services
Documents related:
N/A

Explanation:
Evidence documents conformity to agreed acceptance criteria, supports applicable traceability, and minimizes containment in case of non-conformities or abnormalities.
Supplier Responsibilities:
1. Retain sampling and/or statistical inspection evidence for DENSO identified critical control and special control items. Evidence is provided to DENSO upon request. 2. Inspection evidence is linked to lot shipments / shipment dates / shipment labels. 3. Materials and/or product conformity evidence may be produced by an agreed outside party.

III. Quality Assurance in Trials and Mass Production

III.a Product Shipment Notification - Stratification Control Process

TOC

Purpose:

Product shipment notification is used to notify DENSO that parts/materials differ from previously accepted parts or materials. It is used to identify shipment(s) of affected parts/materials. It is intended for the shipment notification information to remain with the parts/materials throughout the manufacturing process at DENSO (to Final Inspection) to ensure traceability of the modification at DENSO.

Scope:

Adherence to the procedure applies to suppliers of production parts and raw materials as specified in the below table. Stratification Control must be utilized with the parts/materials as specified in the tables below. (Please note the DNMX and DMAT processes on tables 2 and 3, respectively.)

Link to ISO / MAQMSR:

8.7.1.6 Customer notification / 8.5.6 Control of changes

Documents related:

Stratification Control sheet

Explanation:

Stratification Control identifies the use of parts/materials that differ from previously accepted parts due to design or process change, deviation, or any other change affecting the parts/materials or their packaging such as sorted or certified product. **[ISO]:** The supplier shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

Supplier Responsibilities:

Supplier adherence responsibilities table 1:

Plant	Adherence to Procedure Required	Method of Notification	Stratification Requirement per Shipment	Stratification Frequency
ALL DMTN Plants	Y	Form 017 (Stratification Control Sheet) on brightly colored paper	Case by Case (please contact your Quality Representative)	Permanent Change – 1st shipment only; Temp Change/ Certified product – case by case (please contact Q-Rep)
DMMI	N (Contact your Quality Representative for notification requirements)	Not Applicable	Not Applicable	Not Applicable
Other DENSO Plants	Contact your Quality Representative for notification requirement			

Supplier adherence responsibilities table 2 (DNMX):

Plant	Adherence to Procedure Required	Method of Notification	Stratification Requirement per Shipment	Stratification Frequency
DNMX	Y	PCR Form 017(Stratification Control Sheet) on Purple colored paper	1 sheet minimum per each box	1st 3 shipments only
		EC Form 017(Stratification Control Sheet) on Orange colored paper	1 sheet minimum per each box	Permanent change – 1st 3 shipments; Temp Change – all shipments
		DEVIATION Form 017 (Stratification Control Sheet) on Yellow colored paper	1 sheet minimum per each box	Permanent change – 1st 3 shipments; Temp Change – all shipments

		COUNTERMEASURE Form 017 (Stratification Control Sheet) on White paper	1 sheet minimum per each box	1st 3 shipments only

Note: Should DNMX be required to repack material the SQA in charge will require an addition Stratification Control Sheet to be placed inside the packaging.

Supplier adherence responsibilities table 3 (DMAT):

Plant	Adherence to Procedure Required	Method of Notification	Stratification Requirement per Shipment	Stratification Frequency
DMAT	Y	PCR – Strat tag on "Purple" colored paper	1 tag in tote 1 tag on outside tote 1 tag on all 4 sides of pallet * All trial shipments to be palletized individually and wrapped with "red" shrink wrap, unless agreed upon deviation.	1st 3 shipments
		PCR Trial parts – Stop, Call, Wait on "Red" colored paper		All trial shipments
		ESC – Strat tag on "Orange" colored paper		1st 3 shipments
		Deviation – Strat tag on "Yellow" colored paper		1st 3 shipments, temp change all shipments
		Certified stock – Strat tag on "Green" colored paper		Until permanent countermeasure all shipments
		Countermeasure – Strat tag on "White" colored paper		1st 3 shipments

III.b Deviation Request Reply

TOC

Purpose:
The purpose of this section is to inform the supplier how to secure DENSO approval to ship parts or materials that do not meet drawing or specification requirements.
Scope:
This section applies to suppliers of production parts and raw materials to DENSO. This procedure must be followed when the supplier has parts or materials that do not meet all the requirements of DENSO's drawings/ specifications.
Link to ISO / MAQMSR:
8.7.1.1 Customer authorization for concession
Documents related:
Deviation Request Reply

Explanation:
The deviation request is to be used to request DENSO approval for parts or materials that do not meet drawing or specification requirements or other DENSO approved requirements. The supplier is responsible for submitting a deviation request at Mass Production, or if required by your DENSO Quality Representative prior to Mass Production. If any non-conformance is found by the supplier which has the potential to cause shortages of acceptable parts or materials at DENSO, it must be communicated as soon as possible to the DENSO Quality Representative and DENSO Production Control.
Supplier Responsibilities:
1. A deviation represents conditions based on a start and end date, a known quantity/ weight, or die life. The following steps must be followed when submitting a deviation: a. Timing Mass Production: As soon as a non-conformance is found. Pre-Mass: Contact your DENSO Quality Representative for direction. b. Samples Contact your DENSO Quality Representative to see if samples are required or if sample data/pictures is/are sufficient. c. Filling out the Form Complete all applicable sections of the deviation form thoroughly Note: Failure to fill out all areas of the deviation request properly will result in a rejection of the request. **[MAQMSR]**: Also, the supplier shall keep a record of the expiration date or quantity authorized under the deviation. d. The supplier must include any additional supporting documentation (as necessary) that will assist DENSO in evaluating the deviation request. 2. DENSO will evaluate the deviation request and inform the supplier of the decision. Follow instructions provided by your DENSO Quality Representative for shipping deviated parts or materials. 3**. [MAQMSR]** If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to DENSO in the concession or deviation permit. 4. The supplier shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. 5. Material shipped under concession shall be properly identified on each shipping container (this applies equally to purchased product). 6. The supplier shall approve any requests from suppliers before submission to DENSO. Note: 1. If the use of deviated parts/ materials cannot be avoided and DENSO must modify its process, DENSO Purchasing will be involved to address costs incurred by modifying DENSO systems as a result of the deviation.

2. Approved deviations, Including Die Deviations may be revoked if/when usability of product changes during the product life. Examples of changes: Adoption to new line/product changes/updates in tooling for mating parts, variation in materials unavailable during initial investigation time period.
3. A revoked deviation will require strong communication and cooperation between Supplier and your DENSO Quality Representative to establish a plan for tooling correction and implementation to continue mass production.

III.c Boundary, Master, and Material Samples

TOC

Purpose:
This section describes how DENSO and the supplier define acceptance criteria for parts and materials when further definition beyond the drawing or specification is required.
Scope:
This procedure most often applies to parts/material with appearance criteria, especially when visible to DENSO's customer. If DENSO requests boundary or master sample(s), the supplier shall submit sample(s) for mass production level parts.
Link to ISO / MAQMSR:
8.6.6 Acceptance criteria
Documents related:
Boundary, Master, or Materials Sample Form

Explanation:

1. Boundary samples

Boundary samples are used to define the boundary level of a given visual or sensory characteristic difficult to define by quantitative methods. Boundary samples may be temporary or permanent. The boundary sample defines the limit by which a judgment is made to reject or accept a questionable part. DENSO normally operates using boundary acceptable samples.

2. Master samples

Visual parts bear critical importance to customer satisfaction. Master samples define the expectations of DENSO or the customer for part visual characteristics. Master samples are created to control consistency of final product approval.

3. Material samples

The procedures and requirements related to material samples vary on a case by case basis. Please refer to the NQAR or contact your DENSO Quality Representative for specific sample requirements. Please refer to section IV.a of this SQAM for further details.

Supplier Responsibilities:

1. Boundary samples are created on an "as needed" basis when acceptance judgment questions arise.
2. Boundary samples and master samples must be submitted to DENSO Quality under request of the supplier's quality assurance engineer or manager.
3. At least three sets of samples must be submitted to the DENSO Quality Representative. One set will be retained by DENSO and the others returned to the supplier.
4. The supplier stores one boundary / master specimen in a secure manner to prevent daily usage deterioration. DENSO will approve exceptions to this requirement. (Picture e-files do not fall into parts retention scope).
5. Boundary / Master Parts are identified in a manner to prevent accidental shipment.
6. Boundary / Master Parts are catalogued and controlled using gauge and calibration management methods (ISO 7.1.5.2).
7. Each part must be clearly labelled using the form provided. The form may also be reduced and attached to the part(s). A master sample must be mounted such that it can be removed/manipulated for inspection purposes, e.g. by using a clear plastic envelope.
8. For sub-supplier appearance items, the supplier must develop agreeable samples with the sub-supplier for DENSO Quality approval. If necessary, the sample(s) can be developed with DENSO, and negotiated and approved by all three parties (DENSO, supplier, and sub-supplier). Three sets of sub-supplier samples are required, one of each to be retained by each of the parties involved.

9. The sample form must be completely filled out with as much descriptive information as possible, including the supplier approval section. The Log No. and approvals section will be completed by DENSO.
10. Temporary boundary samples may be approved. In such cases, a countermeasure plan must be submitted detailing the problem and corrective actions.
11. Master sample approval is based on visual and/or numerical evaluation. Emphasis is given to visual comparison of the master color and/or mating components. Numerical data forms a basis for benchmarking and tracking process variation. The method used for numerical data collection must be the one which best replicates the operative technique or standard required by the customer.
12. Revisions, changes or renewals must be resubmitted according to the above guidelines.
13. Suppliers are responsible for maintaining color control with a system which documents the color history of parts provided to DENSO and which is in accordance with the master sample.
14. If applicable, the expiration date will be completed by DENSO. When the sample(s) reach the expiration date, the supplier must resubmit the sample(s).

III.d Control of changes

TOC

Purpose:
To the extent necessary to ensure continuing conformity with requirements, the supplier shall review and control changes for production or service provision.
Scope:
This section applies to suppliers of products and/or services sent to DENSO.
Link to ISO / MAQMSR:
8.5.6 Control of changes / 8.5.6.1 Control of changes – supplemental / 8.5.6.1.1 Temporary change of process controls.
Documents related:
N/A

Explanation:
The supplier shall have a documented process to control and react to changes that impact product realization. The effects of any change, including those changes caused by the organization, the customer, or any supplier, shall be assessed.
Supplier Responsibilities:
[MAQMSR]: The supplier shall: a) define verification and validation activities to ensure compliance with DENSO requirements. b) validate changes before implementation. c) document the evidence of related risk analysis. d) retain records of verification and validation. Changes, including those made at suppliers, should 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. When required by DENSO, the supplier shall: e) notify of any planned product realization changes after the most recent product approval. f) obtain documented approval, prior to implementation of the change. g) complete additional verification or identification requirements, such as production trial run and new product validation. **[MAQMSR]: Temporary change of process controls** The supplier shall identify, document, and maintain a list of the process controls, including inspection, measuring, test, and error-proofing devices. The list of process controls shall include the primary process controls and the approved back-up or alternate methods, if back-up or alternate methods exist. The supplier shall document the process that manages the use of alternate control methods. The supplier shall include in this process, based on risk analysis (such as FMEA), severity, and the internal approvals to be obtained prior to production implantations of the alternate control method. Before shipping product that was inspected or tested using the alternate method, if required, the supplier shall obtain approval from the customer(s). The supplier shall maintain and periodically review a list of approved alternate process control methods that are referenced in the control plan. Standard work instructions shall be available for each alternate process control method. The supplier shall review the operation of alternate process controls on a daily basis, at a minimum, to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible. Example methods include but are not limited to the following: a) daily quality focused audits (e.g., layered process audits, as applicable); b) daily leadership meetings. Restart verification is documented for a defined period based on severity and confirmation that all features of the error-proofing device or process are effectively reinstated.

The supplier shall implement traceability of all products produced while any alternate process control devices or processes are being used (e.g., verification and retention of first piece and last piece from every shift).

III.e Process and Design Change Request
Value Analysis / Value Engineering (VA/VE)

TOC

Purpose:
DENSO's VA/VE processes are designed to encourage quality improvement and cost reduction efforts by Suppliers. Specifically, VA is suggested improvements to an existing mass production component, and VE is suggested replacement of an existing design or material. VA/VE Supplier activities are coordinated by DENSO Purchasing Department. The VA/VE Proposal form needs to be completed and submitted in order for Process or Design Change Requests to be considered. This section also explains the procedure for suppliers to request approval for a Process and/or Design change, when Value Analysis/Value Engineering practices take place.
Scope:
This section applies to suppliers of production parts and raw materials to DENSO.
Link to ISO / MAQMSR:
7.5.3.2.2 Engineering Specifications / 8.3.6 Design and development changes / 8.5.6.1 Control of changes
Documents related:
DCR Form from supplier / PECR Request Form / VA VE Proposal Quote Worksheet

Explanation:
The process change request is used by suppliers to request a process change to parts/ materials manufactured for DENSO prior to making the change. It is the supplier's responsibility to submit a process change/design change request to each DENSO facility/plant that uses the part or material. Process change definition can be reference in 1 below. In general, change of machinery location, manufacturing method, trading companies , cleaning agents, etc. are regarded as process changes, whereas changes in material (manufacturer, grade, specification) may be regarded by DENSO as design changes. Change requests for items specified on a drawing issued by DENSO are considered design change.
Supplier Responsibilities:
Suppliers are encouraged to work with DENSO to improve quality and reduce costs. Participation in VA/VE will result in Suppliers being able to receive a portion of the cost savings associated with these activities, and increase their Supplier Performance Score. The supplier must submit a process change request to DENSO Purchasing as soon as it is clear that the supplier would like to have a process change or design change considered. A minimum of 4 months is recommended in advance of the proposed process change. Please note, however, that approval or disapproval of a process change request may take considerably longer than this depending on testing requirements or customer specific approval requirements. PCRs that do not result in a cost reduction or tangible quality improvement, but are requested by the supplier may incur a fee. At DENSO's discretion, the cost that will be incurred by DENSO to evaluate and test this type of PCR will be calculated and given to the supplier along with the Initial PCR Response. If the supplier wants to proceed with the proposed PCR, payment for the evaluation and test cost will need to be made to DENSO prior to the start of the PCR evaluation and testing. Examples of a PCR which generally would not result in an evaluation fee or test fee. Examples of a PCR that could result in an evaluation fee and test fee: Supplier wants to move production of DENSO part(s) from Plant A to Plant B for plant optimization, but there is no cost reduction or tangible quality improvement for DENSO. o *PCRs that cost DENSO money to evaluate and test, but are of no benefit to DENSO. o Examples of PCR evaluation and testing cost that can be charged: • Manpower labor cost (ISIR, reliability testing and coordination) • Trip cost to review process change (flight, drive, hotel, pier diem, out of office time) • Equipment (reliability testing) • Part (reliability test assembly cost) o *Most PCRs will not incur an evaluation fee or test fee. o Examples of PCRs that may not result in an evaluation fee or test fee:

- Cost reduction, quality improvement, die renewal, new tooling, material obsolescence, etc.

A process change is defined as, but not limited to the following:

a. Change of manufacturing equipment (New/Refurbished/Different).

b. Change of manufacturing process (Process sequence, Conditions, etc).

c. Change of material suppliers or material trading companies.Note: However, if the DENSO issued drawing indicates a specific grade number or manufacturer of raw material, then this change will be considered as a Design Change Request and will require further documentation.

d. Change of chemicals or sub materials used in the manufacturing process (etching, cleansing, heat treating, plating, etc...). Note: Heat treatment and surface treatment are considered as special processes within DENSO and may be considered as Design Change, pending the nature of said change.

e. Change of process/equipment/material at subcontractor. Note: If material at subcontractor is specified by DENSO, this is also considered as a Design Change.

f. Supplier's in-house production is sub-contracted or vice versa.

g. Change of inspection method.

h. Any changes that DENSO judges a process change.

A design or engineering change is defined as, but not limited to the following:

a. Alteration made to a bill of materials by:
   i) adding or deleting an item (assembly, sub-assembly, component, or material),
   ii) substituting an item with another, or
   iii) changing the usage of an item.

b. Alteration made in the functional, maintenance, performance, or physical characteristics of a system.

c. Any changes that DENSO judges a design change.

Note: *Please reference the table at the end of this section for further definition of a Process / Design change. If the supplier is unsure whether a change requires the submittal of a process change request they should contact the* DENSO *Quality Representative for directions. Again, any change related to a notation on a DENSO drawing is considered as a design change, requiring additional documentation and evaluation by all parties.*

Note: *Supplier is not to fill out the Process Change Request Number, this is done by* DENSO.

- The supplier must fill out the top portion of the process change request
- The supplier must attach any additional supporting documentation including planning for quality confirmation testing and a process change implementation schedule.
- The process change request and supporting documentation must be approved by the supplier's Quality Assurance Manager or equivalent. Consideration should be given when developing the proposed implementation schedule for the time that will be needed by DENSO to conduct initial internal testing. The supplier's DENSO Quality Representative may be able to assist the supplier in determining how much time will be needed for these internal activities.

- Once the process change request is received at DENSO, it will initially be reviewed for acceptability and additional requirements determined including consideration and confirmation if the request is only a process change or if it is a design change. DENSO will fill out the Initial Response or Plan Approval section and return a copy to the supplier. The supplier must submit all items required by the due dates specified on the process change request. No further consideration will be given to the process change until all items are completed to DENSO's satisfaction.
- Once all items are received, DENSO will review, perform measurements/testing and make a final judgment on the process change request. A copy of the process change request or design change request with the final judgment will be sent to the supplier. The DCR may include a DENSO Engineering Change Instruction (ECI) and new drawings/specifications. In most cases a description of the ECI process will be provided by Purchasing. Suppliers are not authorized to implement any process change or design change until they receive the approved PCR/DCR form from DENSO. Contact your DENSO Quality Representative for specific requirements regarding your PCR/DCR.
- Follow your DENSO Quality Representative's direction as to what type of labelling or marking is required of initial shipments.

Items requiring process change notification (Notes section following this table includes items which are also considered as design change):

5M1E \ Process	Stamping Caulking Forging Parts	Cutting Parts	Plastic Molding Casting Parts	Welding Parts	Rubber Brush Sintering Parts	Surface Treatment Parts	Heat Treatment Parts	Soldering Parts	Assembling Parts (Electronic Parts)
Man									
Machine – Equipment	Transfer to other plant and additional installation								
Machine – Die, Jig & Tool	1. Change from manual procedures to automated process 2. Change/alteration of equipment								
Materials – Supplier & Plant	1. Change of Material Manufacturer or Trading Company 2. Change of Material Manufacturing Equipment Process Conditions 3. Maintenance of Material Manufacturing Equipment								
Materials – Content & Inspection	Change of raw materials/chemical compositions, including: a. Impurities b. Change of inspection methods/items								
Method	1. Change of in-house and/or outsource category 2. Change of cleaning method 3. Change of processing method (including change of number of cavities) 4. Process change at secondary and subsequent suppliers 5. Change of processing conditions* 6. Change of processing sequence 7. Change from "Temporty process" to "Normal process" 8. Change of previous processing method**								
Inspection and Measurement	1. Change of Inspection Jig 2. Change of Inspection Jig (including in-process sizing jig) (applies to Plastic Molding & Casting Parts) 3. Change of Welding Monitor (applies to Welding Parts)					1. Installation and change of Inspection Device 2. Change of inspection item (Applies to Assembling Parts (Electronic Parts)			
Environment	1. Increase of power transformer load due to additional installation of Equipement (applies only to Welding Parts, Heat Treatment Parts & Soldering Parts)								
Remarks	* Method - Conditions: Temperature, pressure, electric power, voltage, current, speed, density, time, and others. ** Manufacturing process: Notification must NOT be submitted for new parts to change from "Temporary process" to "Normal Process"								

Note: Items requiring Design Change shall include (but are not limited to) all items currently specified on a DENSO issued drawing, such as:

- Resin materials (specified by DENSO for either in-house use or for use at an outside molder)
- Materials and/or processes that are used in critical parts (as specified by DENSO)

III.f Rework and repair procedure

TOC

Purpose:
To specify control methods for guarantee of quality when there is deviation from the normal process flow in order to rework or repair the product.
Scope:
This section applies to suppliers of production parts or raw materials to DENSO.
Link to ISO / MAQMSR:
8.7.1.4 Control of reworked product / 8.7.1.5 Control of repaired product
Documents related:
N/A

Explanation:
Rework is defined as any temporary steps taken outside of the documented process flow on product that will ship to DENSO. Because rework is abnormal, it must be carefully controlled in order to guarantee quality. Rework, repair, & teardown processes, re-use processes require DENSO pre-approval. Definitions & activities identified (PFC-PFMEA-PCP-W.I.-Training) and approved at PPAP are considered pre-approval. The PCP shall identify set-up, specifications, process parameters, and controls for non-routine activities. Characteristics with Critical Control Classifications are confirmed with same inspection equipment or acceptance methods as normal production. Changes to the process should be requested through PCR or approval method should be confirm by DN QE Representative Permanent changes to the process should be requested through a Process Change Request (see section III.e)
Supplier Responsibilities:
[MAQMSR]: The supplier shall utilize risk analysis (such as FMEA) methodology to assess risks in the rework / repair process prior to a decision to rework / repair the product. The supplier should develop, maintain, and follow a general rework procedure that is available to your DENSO Quality Representative upon request. This procedure should include, but is not limited to: a) Requirements for specific rework/repair instructions for each rework/repair event. b) Requirements for a rework and repair record. These records should include the rework and repair instructions, rework and repair details, lot information, and quality check result of the reworked / repaired product. This record should be readily available if requested by your DENSO Quality Representative. c) Requirements for identification method for reworked / repaired parts. DENSO preference is that each part be identified indicating rework / repaired occurred. **See table below of rework guidelines. Contact your DENSO Quality Representative with any questions.

REWORK GUIDELINES	
Item	**Guideline**
Workplace	1. There shall be a special defined workplace for rework, unless it occurs on mass production equipment. 2. Products before rework, reworked products and rejected products shall be sorted by allocating the different space for the work piece, separating boxes by color, identification of the actual product, etc. 3. Necessary equipment and tools for rework shall be provided. (This shall be specified on the rework instruction sheet.) 4. Workplace environment, like lighting, shall be provided so that the work and its check can be ensured. 5. As possible, rework, repair, & teardown, re-use parts are re-introduced prior to their removal point. (When possible perform at

	start of production – re-introduce at start of production) Include all quality confirmation test.	
Rework instruction sheet	1. There shall be a rework instruction sheet. 2. The product to be reworked ('rework item') shall be specified. The maximum quantity of reworks, repairs, re-try's, or re-uses shall be defined. 3. Work steps and work details shall be specified for each rework item. (potential negative influence by rework operation should be considered) 4. Distinguish and define non-reusable from reusable parts. Re-useable vs non-re-useable parts shall be defined. 5. A check procedure for reusable parts shall be specified. 6. An inspection procedure for reworked products shall be specified. 7. Specify when, where and how to put reworked products into the normal line. 8. All the items of a reworked product shall be inspected at the normal inspection process. 9. When a product is disassembled and reloaded, checking method for preventing wrong parts shall be clarified (like identification, indication and controlling methods of the extra parts and space). 10. Rework and re-use parts should be used as soon as possible (on the same shift is preferred)	
Operator	1. The operator certified for rework shall be specifically trained. Training records should be kept, and made available to the DENSO Quality Representative upon request. 2. The operator can and shall work according to the work instruction sheet. 3. The operator shall understand that unusual failure modes different from the usual ones shall not be reworked and shall be reported and shared. 4. The operator shall understand that a special action is necessary (like using an identification control tag) in case of a rework interruption.	
Identification record	1. The rework record shall include part no., date, reworking details **[MAQMSR]** (e.g. disposition, disposition date), product quantity and operator name (this step can be omitted for the rework inside the line). 2. Control the reworked products so that they can be sorted with clear identification etc.	

III.g Trouble Shooting and Abnormalities

TOC

Purpose:
This section describes DENSO's requirements for preventing outflow of nonconforming product in the case of abnormal conditions in the manufacturing process, and the need for specific procedures concerning this important topic.
Scope:
This procedure applies to suppliers of production parts and raw materials to DENSO.
Link to ISO / MAQMSR:
10.2 Nonconformity and corrective action
Documents related:
N/A

Explanation:
"Abnormal condition" is defined as any situation where the manufacturing process is different than the PPAP approved manufacturing process that may cause a problem in the quality of the parts, customer rejections, line stop, delivery stop or potential safety risk. [ISO]: This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. Examples include the following: 1. A specific piece of equipment is not functioning properly, so some minimal (Work-In-Process) WIP is stored until the piece of equipment is repaired. 2. A specific assembly fixture is briefly out of service for repair, and an alternate method of assembly (hand assembly) is utilized so shipments are not missed. 3. Due to labor conditions, temporary or alternate personnel are trained to perform manufacturing or assembly processes.
Supplier Responsibilities:
Since abnormal conditions frequently cause downstream quality issues, DENSO requires each supplier develop a specific procedure concerning controls required in the case of the occurrence of an abnormal condition. These controls must include: 1. Identification and communication of abnormal conditions to proper managerial levels/ functions within the organization and to your DENSO Quality Representative. 2. Communication plan should include approval/feedback from internal organizational as well as approval from DENSO Quality Representative before any abnormal production and/or parts shipment under abnormal conditions occurs. 3. Special activities to ensure quality levels are maintained until such time as the normal process resumes. These controls shall also ensure all affected product is contained until such time as quality levels can be confirmed. Additionally, troubleshooting activities and responsibilities should also be included in the procedure to determine cause of abnormal conditions and prevention of future occurrences. 4. Supplier shall report to DENSO Quality Representative when process/shipments return to normal PPAP approved process. Examples: 1) Maintaining production when pokayoke not operating (Requiring temporary special controls such as manual inspection or off line test). 2) Maintaining production when key production fixture not available (Requiring special temporary process). 3) Parts with minor deviation (minor visual issue for example) that may be acceptable for customer use (Avoid scrap) – Temporary deviation.

III.h Nonconforming Product Communication and Corrective Action Process

TOC

Purpose:
The purpose of this procedure is to describe the means of communicating required corrective actions for supplier responsible nonconforming parts or material, describe the DENSO Defect Containment Assurance Program (DCAP), describe the DENSO Reaction Plan to suppliers who have nonconforming and/or quality management system issues and describe how DENSO will chargeback for costs incurred due to nonconforming parts or material.
Scope:
This section applies to all supplied products (e.g. raw material, components, assemblies, etc.) that have been deemed to be nonconforming by DENSO, or by a DENSO customer. DCAP will be applied to all supplied products that have a defect history that warrants special containment measures (as determined by your DENSO Quality Representative's Management).
Link to ISO / MAQMSR:
8.7, 8.7.1 Control of nonconforming outputs / 8.7.1.2 Control of non-conforming product – customer specified process / 8.7.1.3 Control of suspect product / 8.7.1.6 Customer notification / 10.2, 10.2.2 Nonconformity and corrective action / 10.2.5 Warranty Management Systems / 10.2.6 Customer Complaints and field failure test analysis / 10.2.3 Problem Solving
Documents related:
Corrective Action Forms (QFAS/FCAR/PCAR)

Explanation:
Nonconformance is defined as product or material that has not fulfilled the requirements of the associated specification(s), drawings, NQAR or this SQAM. Suppliers of nonconforming product or material must establish robust process and system improvements to prevent the suspect product from being used, transferred, or installed. The following items must be addressed: 1) Evaluation 2) Identification 3) Containment (If necessary, update risks and opportunities determined during planning and/or make changes to the quality management system) 4) Corrective and Preventative actions to prevent recurrence (If necessary, update risks and opportunities determined during planning and/or make changes to the quality management system) 5) Across Line Actions 6) Verification of Effectiveness Required corrective actions will be guided and monitored by DENSO Plant SQE. **[MAQMSR]** NOTE: The supplier shall ensure that all appropriate manufacturing personnel receive training for containment of suspect and nonconforming product.
Supplier Responsibilities:
1. When nonconforming product or material is found at DENSO (Receiving, Trials, Manufacturing or Assembly disruption), at a DENSO Customer Site (0km or 0mile) Claims or in the field: A. DENSO will formally communicate nonconforming material issues using: Quality Failure Notices (QFN), Part Corrective Action Request (PCAR), Quality Claim or a Field Corrective Action Request (FCAR) formats. Your DENSO Quality Representative will inform you as to which form is used at their facility. Note: These documents are system related at the various DENSO facilities, so they may vary in format. The format used will have a ranking. Generally defined as follows: S = Critical: Regulatory Customer Failures A = Very Serious: Line stoppage or high quantity, government regulation, high severity B = Serious: Functional rejection or repair required C = Moderate: Noticeable appearance defects D = Appearance (non-visible parts), low quantity

B. Supplier required initial response time:
"S" and "A" rank issues – 24 hours
On all other issues (you will be notified on response timing requirements by your DENSO Quality Representative.

C. All responses must include the following information:
i. Confirmation of defect mode
ii. Emergency Response Action(s) or containment activities
iii. Countermeasures:

a) The supplier shall take immediate corrective actions for the parts or raw material at the supplier's facility and at appropriate DENSO facilities and/or DENSO Customer, if applicable. The supplier must immediately inform DENSO if any suspect parts are potentially in-transit to DENSO.
b) Certified shipments may be required until permanent corrective actions have been implemented. Notification of shipment timing must be communicated to your DENSO Quality Representative. ASN or Delivery Order Number may be required as needed.
c) The supplier is required to sort inventory at DENSO and DENSO Customers when requested by DENSO Quality. If DENSO is required to rework/sort any non-conforming parts or product at DENSO or DENSO's customer, DENSO may charge the supplier for this rework/sort activity.
d) If any part is found to be nonconforming, the supplier is responsible for reworking or replacing the part. Rework of such part may be required at DENSO, DENSO Customers and at the supplier. Before any rework is begun, the rework and marking methods must be approved by DENSO Quality.

d. Corrective actions reporting:
i. The form used for reporting corrective actions are one of the following: QFAS (Quality Failure Answer Sheet) Form, Global 8D, Quality Claim, or PCAR format. Updating the appropriate documents, such as FMEAs, control plans & QA Networks, may also be required by your DENSO Quality Representative.
ii. The supplier's quality assurance manager or above must approve the response. The supplier may decide any other appropriate signatures.
iii. The response should be sent to DENSO Quality Representative by the due date listed, whether or not the permanent corrective actions have been determined.
a) If the response is not a final response (lacking permanent corrective actions), the supplier should indicate it is an initial response.
b) Temporary corrective actions must be reported, along with a scheduled date for permanent corrective actions to be reported.
c) The supplier should follow up with DENSO Quality Representative and report permanent corrective actions as scheduled.
[ISO] NOTE: Conformity to the requirements shall be verified when nonconforming outputs are corrected.
[MAQMSR]: The supplier shall communicate the results of testing/analysis within their organization.

2. When non-conforming product or material is found in the field (Warranty):

A. DENSO will formally communicate non-conforming material issues using:
Quality Failure Notices (QFN) or a Field Corrective Action Request (FCAR) formats. Your DENSO Quality Representative will inform you as to which form is used at their facility. An Investigation Report is required in addition.

B. Investigation Report Requirements
a) Investigation results must be in a technical report format, unless otherwise instructed by your Denso Representative. The supplier should include any other checks they determine necessary.
b) For No Trouble Found (NTF) parts; a report stating NTF with no supporting data will NOT be accepted. At a minimum, functional/performance data, disassembly results and other testing related to the defect must be included.

c) Investigation reports must be returned by the due date provided to the supplier by DENSO. This date is normally related to DENSO's customer due date. Late responses can result in warranty charges by some of DENSO's customers. Any costs resulting from late responses WILL be charged back to the supplier. If the due date cannot be met, contact your DENSO representative several days before the due date to request an extension.
d) Most DENSO plants require that the Tag #, VIN #, part number and production date be included in all reports. (Note: If multiple parts are returned on the same report, this identification must be associated to each individual part). Please contact you DENSO Quality Representative for their specific requirements.

C. **[MAQMSR]** Where requested by DENSO, this shall include analysis of the interaction of embedded software of the supplier's product within the system of the final customer's product.

[ISO] NOTE: The supplier shall retain documented information as evidence of the nature of the nonconformities and any subsequent actions taken and the results of any corrective action.

DENSO Reactions to Supplier Non-Conformances or Failure to Meet SQAM:

This SQAM is part of the DENSO Purchase Order and therefore are general terms and conditions of doing business with DENSO. The Supplier is liable for all direct and indirect damages, losses, costs, and expenses incurred by DENSO resulting from the failure of the Supplier to deliver conforming goods.

DENSO does not entertain financial charge backs lightly and always keeps supplier's partnership and financial future in mind. Whether at DENSO facility, customer site claims (0km or 0mile) or warranty, common costs could be (but not limited to): inspection labor, off lining of goods, interruptions or delays in production, reduced line-speeds, plant shut-downs, 3rd party companies demanded by OEM or tiered suppliers or DENSO or it's suppliers, increased freight to deliver conforming product and OEM administrative fees.

Costs might be incurred by (but not limited to): Aftermarket retail parties, OEM dealerships, OEM service part warehouses, OEM vehicle plants, tiered suppliers, DENSO or its suppliers.

1. Warranty Cost Charge Back
Charge backs will be based on actual returned parts OR ratios established from returned parts. The supplier may also be charged for the shipping costs of returned parts.

2. DENSO Customer Site (0km or 0mile) Claim Charge Back
The supplier is also liable for any costs charged back from OEMs to DENSO.
3. DENSO Facility Receiving, Trials, Manufacturing or Assembly Charge Back
The supplier is also liable for any costs with having to inspect product using DENSO associates or 3rd parties until the supplier contracts or provides inspection labor.
4. Defect Containment and Assurance Program (DCAP)
DCAP is an additional inspection program to assure containment and protection of DENSO and/or its customer from receiving defects. A supplier will be notified of this requirement via a DCAP Launch Notification Letter. There are 2 levels of DCAP.
DCAP Level 1: Additional inspection performed at the supplier by supplier resources. This inspection must occur outside the normal process beyond normal inspections.
DCAP Level 2: Additional inspection performed by a 3rd party. All costs paid by supplier.
DENSO may place a supplier on DCAP with little or no advance notice. Careful consideration is given by DENSO Management prior to placing a supplier on DCAP.
5. Non-Conforming Cost Charge Back

The supplier is liable for all direct, incidental and consequential damages, losses, costs, and expenses incurred by DENSO resulting from the failure of the Supplier to deliver conforming goods. These include - but are not limited to - costs associated with re-inspection, rework or off lining of goods, interruptions or delays in production, reduced line-speeds, premium freight and plant shut-downs both internal and external to DENSO (it's customers and other suppliers).

Supplier Responsibilities (Relative to DCAP):

A. DCAP Notification Letter: The supplier must acknowledge receipt of the DCAP Notification Letter in writing, by returning the Confirmation Notice along with their containment plan. This containment plan shall be reviewed and approved by DENSO.
B. DCAP Execution: The supplier will implement the DENSO approved containment plan. Inspection data must be collected by the supplier and submitted to the DENSO Quality Representative. Any defects found in the containment inspection must be reported to the DENSO Quality Representative, along with process control breakdown investigation and corrective actions taken. This continues until the DCAP release criteria are met.
C. DCAP Release: The supplier must request a release from DCAP totally or defect-by-defect when the release criteria are met, as stated in the DCAP Notification Letter. The DENSO Quality Representative will review release criteria, and when satisfied, sign the Request for Release document. In the case of DCAP2 release, the supplier may have to continue DCAP1 extra inspection as determined by the DENSO Quality Representative.

1. Reaction (Escalation) Plan Guidelines: DENSO NA Plant Quality Departments will follow an escalating guideline to deal with poor supplier performance. Although the guideline is considered, it is not mandatory and serves more as a model for consideration than a mandatory rule. Please see Table 1.

		Denso NA			Supplier		
Escalation Level	*To enter next level or remain in this level*	*Tool*	*decide*	*Time*	*Tool*	*Time*	*previous level*
Level 0	Quality Concern	QFN, PCAR & FCAR	Denso NA Plant QE	Immediately	QFAS, PCAR & FCAR	Denso NA Plant Requirement	N/A
		Scorecard	QE & Purchasing Depts	Quarterly	N/A	N/A	N/A
Level 1	Quality Concern	QFN, PCAR & FCAR	Denso NA Plant QE	Immediately	QFAS, PCAR & FCAR	Denso NA Plant Requirement	N/A
	Quality Targets (Scorecard) 1x-3x beyond Specific Denso NA Plant Requirement	DCAP Level 1 Notification Letter	Denso NA Plant QE	Monthly	Certification Details	Each Delivery	>1 month OK
		DCAP Level 2 Notificaiton Letter	Denso NA Plant QE	Monthly	Certification Details	Each Delivery	>2 months OK
		Short-Term Improvement Plan	Denso NA Plant QE	Monthly	Improvement Plan	Monthly	1 year KPI's OK
	Quality Concern	Scorecard	Depts	Quarterly	N/A	N/A	N/A
Level 2	Quality Concern	QFN, PCAR & FCAR	Denso NA Plant QE	Immediately	QFAS, PCAR & FCAR	Denso NA Plant Requirement	N/A
	Quality Targets (Scorecard) 4x or worse beyond Specific Denso NA Plant Requirement	DCAP Level 1 Notification Letter	Denso NA Plant QE	Monthly	Certification Details	Each Delivery	>1 month OK
		DCAP Level 2 Notification Letter	Denso NA Plant QE	Monthly	Certification Details	Each Delivery	>2 months OK
		Long-Term Improvement Plan	Denso NA Plant QE	Quarterly	Improvement Plan	Monthly	1 to 3 years KPI's OK
		Business Reduction or Hold	QE & Purchasing Depts	Quarterly	Unique Case-by-Case	Varies	Denso NA Plant Requirement
	Quality Concern	Scorecard	QE & Purchasing Depts	Quarterly	N/A	N/A	N/A

TABLE 1 – SUPPLIER REACTION PLAN

III.i Record Retention

TOC

Purpose:
The purpose of this section is to define the DENSO North American record retention requirements for all parts and materials suppliers. Additional requirements may exist and also apply for individual DENSO sites and programs, and will be conveyed as necessary.
Scope:
This section applies to suppliers of production parts and raw materials to DENSO.
Link to ISO / MAQMSR:
7.5.3.2.1 Record Retention
Documents related:
N/A

Explanation:
This section is to clearly define supplier record retention guidelines in order to align with automotive industry requirements.
Supplier Responsibilities:
1. Suppliers must assess their current practices and adjust policies and procedures to match the retention requirements listed hereafter. 2. Suppliers must keep records organized, protected from environmental elements, and readily available if requested by DENSO. Storage preservation methods may by hard copy (permanent marking) and/or electronically, although electronical is deemed as a more reliable, safe, and effective storage method. 3. The supplier must retain the below quality, product and process design records: a. Adequate quality process control system records, including, but not limited to: • All PPAP documentation, incoming material certifications, tooling records, lot control records (down to raw materials and sub-components), manufacturing conditions, work instructions, quality alerts, poka yoke & master checks, TPM records, corrective & preventative actions, inspection/test results (including annual validations, process control charts, capability studies, etc.), shipping records, rework/abnormal condition information, and nonconforming/defective parts records (including customer complaints) with applicable countermeasures. b. Product & Process Design Records • Drawings • Specification Sheets c. Change Management • 5M-1E change logs • Change points • Verification & Validation Testing. 4. Quality records for non-GM parts should be retained for a minimum of 20 calendar years from when they were created. Quality records for GM parts require a minimum of 50 years record retention. If necessary, please consult your DENSO Quality Representative contact to confirm appropriate retention times. The supplier agrees to transmit to DENSO, those records kept in support of DENSO work, even in the event that the supplier discontinues business operations. 5. Other internal records, such as internal quality audits, training records, and management reviews shall be retained for 3 years from creation for the OEMs. Honda training records shall be maintained for 20 years. 6. 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. The above does not supersede any regulatory requirements. The above time periods are considered “minimum.”

IV. Other requirements

IV.a Special Section for Materials Only Suppliers

TOC

Purpose:
DENSO's philosophy for the quality assurance of material extends to not only raw material used within DENSO facilities but also to those materials specified by DENSO made into parts supplied to DENSO. DENSO has taken efforts to develop and maintain a quality assurance system encompassing a range of activities, from the development, design, and prototype production of new products, to mass production, sale and after servicing, to provide a level of product quality that fully satisfies our customers. Our suppliers must fully understand DENSO's concept of quality assurance by providing reliable products, enhanced credibility, and improved standards within their respective companies. We hope you will secure a perfect quality assurance system through your efforts with DENSO.
Scope:
This section applies to suppliers of raw materials to DENSO as well as materials for parts that are specified by DENSO (as indicated in DENSO drawings released to said suppliers).
Link to ISO / MAQMSR:
8.2.2 Determining the requirements for products and services
Documents related:
N/A

Explanation:
All materials suppliers and materials suppliers' support personnel are required to abide by the guidelines put forth in this policy. If there are any questions about specific materials supply, contact your DENSO Quality Representative.
Supplier Responsibilities:
1. Provide materials with a high level of quality that has been assured by the supplier and approved by DENSO. 2. Take full responsibility for the production of materials that fulfill DENSO quality requirements, and deliver these materials to DENSO (and to our parts suppliers), in accordance with Material Specification documentation. 3. Establish and maintain a quality assurance system that can secure a constant level of materials quality, while appropriately controlling quality fluctuations, in order to ensure the quality of the material provided to DENSO. 4. Acknowledge Material Specification Documentation upon request from DENSO. Additionally, Material Specification documentation must be used when (unless otherwise agreed upon with your DENSO Quality Representative): a) A material is being used for the first time. b) The type or quality of the material has changed. c) The sub-supplier of the material has changed, or a new supplier has been added. d) The standard size of the material or allowable deviation has changed. e) The quality assurance requirements, chemical components or characteristic values of the material have changed. f) The container shape for production or transport of the material has changed. g) Test and inspection methods have changed. h) The location of the factory (company) providing the material has changed. Note: If material specifications have not arrived prior to start of production, the supplier must immediately contact their DENSO Quality Representative. 5. Issue a Materials Test Report a) As a general rule, test results should be reported in accordance with the agreed upon content of the Material Specification. If there are items to be changed, or items that cannot be disclosed, please inform your DENSO Quality Representative. b) Typical examples of Materials Test Report include: Certificate of Analysis, Mill Sheet, etc. Your DENSO Quality Representative can provide direction. c) The Materials Test Report should be submitted to DENSO prior to the delivery date of the material and be designated with the appropriate lot number corresponding to the material received. d) Please note that a Materials Test Report for items designated as early stage control items or critical point control items should always be disclosed.

6. Store and maintain the Material Specification documentation, drawings (if applicable), and inspection standards with updated versions to ensure appropriate inspection and data submission is performed.
7. Change requests to material specifications or any other material inquiries must be made following the Process and Design Change Request (PCR/DCR) procedures outlined in Section III (d) of this SQAM. Material specification changes must be approved by DENSO prior to supplier implementation. Depending on the nature of the specification change, many departments within DENSO may be involved (Product Design, Quality, Production, Materials Engineering, etc.); therefore, material specification change requests to DENSO must have strong viable reason. Final agreement upon material specification changes shall be communicated to the supplier through DENSO purchasing representative.
8. Comply with Inspection Sample Submission
   a) As part of DENSO's incoming raw material inspection process, the supplier may be requested to provide appropriate samples for evaluation including:
      i) Test bars (depending on material: molded, cured, or stamped)
      ii) Small sample quantity set aside (depending on material: pellets, sample vial, etc.)
   b) Your DENSO Quality Representative and/or a Purchasing Representative will communicate to you the requirements for Inspection Sample Submission including sample type, quantity, packaging, etc.

IV.b Substance of Concern (SoC) Requirements

TOC

Purpose:
The purpose of this section is to define the Substance of Concern (SoC) requirements and explain the corresponding processes and procedures.
Scope:
This section applies to all suppliers of production component parts and raw materials.
Link to ISO / MAQMSR:
8.2.2 Determining the requirements for products and services.
Documents related:
N/A

Explanation:
OEMs mandate that suppliers report recycled content, recyclability, and restricted and reportable substance content in parts shipped to them for the purpose of dismantling, recycling and substance certification. DENSO, as a Tier I supplier, is required to cascade these reporting requirements to sub-tier suppliers and coordinate the reporting of this requested data to the OEMs. To facilitate these various customer-reporting requirements, DENSO requires suppliers to utilize the International Material Data System (IMDS) to report this information. In some special cases, DENSO may request suppliers to provide data in a separate format. IMDS is a secure on-line application and is the automotive industry's standard format for sharing data necessary to demonstrate compliance to global regulations and customer requirements. Information which is reported in IMDS includes Bill of Materials (BOMs), materials of composition, and chemical make-up of those materials. The Substance of Concern (SoC) requirements outlines the material/substance IMDS reporting requirements, and the restrictions on the use of substances of environmental concern in production parts, components, and raw materials.
Supplier Responsibilities:
1. DENSO North America Statement of Environmental & Safety Requirements Supplier to comply with the DENSO Supplier Environmental and Safety requirements as stated in the "DENSO General Terms & Conditions Agreement", and in the "DENSO North America Statement of Environmental & Safety Requirements" (see Table 1). 2. DENSO Design Standard 2004 Requirement Supplier shall comply with DENSO Design Standard (DDS) 2004, "Restrictions on Use of Substances of Environmental Concern as Materials or Product Components" (see Table 1), for all production parts, components and raw materials sold to DENSO. DENSO shall make the most current version of DDS2004 available for supplier within the DENSO NA website. This is a secure document and requires a password for access. Passwords are available in 6. Related Documents of this section. It is the supplier's responsibility to read and understand this standard. Table 1: Requirement Table

Requirement	Explanation
*DENSO North America Statement of Environmental & Safety Requirements	DENSO North America's minimum environmental & safety requirements
DDS2004 (password protected)	DENSO Design Standard for restrictions on the use of substances of environmental concern as materials or product components.

DIS2320 (password protected)	DENSO analysis method for substances of environmental concern. This form may be required – contact your DENSO Quality Representative for details

**NOTE: Requirement Document Located in Appendix*

3. IMDS Reporting Requirements

This section provides DENSO specific IMDS reporting requirements. This section supplements the Recommendations and Help pages, available on the IMDS website.

a) Reporting Part, Material, and Substance

IMDS data reporting requires suppliers to provide the part structure (BOM) for assemblies and subassemblies down to individual component level parts. Individual component level parts are then defined by their materials of composition, and materials are defined by their chemical composition (i.e. substances). In addition, suppliers are required to report materials utilized in the manufacturing process. This would include all materials included on the product as utilized in vehicle, such as solders, paints, oils, lubricants, adhesives, inks (ex: on labels or used as inspection marks) etc. Materials which are not included on the product as utilized in the vehicle are not required to be reported (ex: shipping caps).

To complete an IMDS data submission, the following information is required:

- Part structure (BOM) for the final product shipped to DENSO
- Part weights (and sub-component part weights, if applicable)
- Materials and quantity of each material used in individual component level parts and materials utilized in the manufacturing process
- Chemical composition of the material (CAS# and chemical names)

For any part number supplied to DENSO, it is the responsibility of the supplier to DENSO to coordinate the data collection from their sub-tier suppliers and consolidate the reporting results on a single IMDS data submission. DENSO will not coordinate this activity for suppliers to DENSO.

b) IMDS Access

IMDS can be accessed via the internet at www.mdsystem.com. A user ID and password are required for access which can be obtained by contacting an IMDS Service Center. Reference materials and instructions are available on the IMDS Information Pages, which can be accessed from the home page.

c) IMDS Data Submission Guidelines

IMDS data submissions to DENSO must meet the minimum requirements of the IMDS Recommendations as identified on the IMDS website. Suppliers should pay particular attention to the data requirements for structure and disclosure as outlined in IMDS Recommendations 001. IMDS Recommendations are available for download from the IMDS Recommendations page.

IMDS data for an individual part or sub-assembly must be submitted as a component. Items supplied to DENSO such as adhesives, paints, oil, or other raw materials which require additional processing by DENSO must be reported as either a semi-component or material. Materials should be reported in the finished or cured state as they exist on the product as utilized in the vehicle (ex: solvents which may evaporate should not be reported).

The polymeric parts marking question must be answered for any component that contains more than 5 grams of a polymeric material (for IMDS material classifications of 5.x)

DENSO suppliers are required to utilize IMDS to report part, material, and substance information for the following:

- Current Production Parts/Materials
- Modification to Production Parts - Prior to production part modifications when there is a change to: 1) DENSO part number, 2) material content, 3) substance composition, or 4) change in the mass of a part exceeding the tolerance listed on the production part drawing.

- New Product Initial Sample Submissions (PPAP/ISIR) – Effective 12-31-03, DENSO suppliers are required to submit IMDS data for all PPAP/ISIR parts.

IMDS data must be submitted to DENSO International America, Inc. IMDS ID 203123, via the Send (allows one recipient) or Propose (allows several recipients) options. Table 2 below identifies data fields which are required and optional for IMDS data submissions.

Table 2: Required IMDS Data Fields

Field Name	Description	Required/ Optional
Recipient	DENSO International America, Inc	Required
Company/Org ID	203123	Required
Part/Item No.	DENSO part number, typically 12 digits (two letter prefix followed by 10 numbers). Hyphens (-) or blank spaces should NOT be included in DENSO part numbers. ex: TN1234567890 (correct) vs. TN 123456-7890 (incorrect)	Required
Description	Part name as provided by DENSO (as it appears on the drawing)	Required
Drawing No.	Drawing number of this part	Optional
Drawing Date	Date of part drawing	Optional
Drawing Change Level	Change level of part drawing	Optional
Report No.	Number of the First Sample Approval Reports for the product (of which this IMDS submission may form a part)	Optional
Date of Report:	Date of the First Sample Approval Reports	Optional
Purchase Order No.	DENSO purchase order number referencing this part	Optional
Bill of Delivery No.	Bill of delivery number referencing this part	Optional
Supplier Code	Supplier code as provided by DENSO, typically DENSO plant code (DMTN, ANC. etc.) + DENSO plant assigned supplier number (e.g. DMTNP03)	Optional

a) IMDS Data Acceptance/Rejection

Suppliers should check whether IMDS data submission to DENSO has been accepted or rejected. Rejected data must be revised according to the reasons for rejection, and resubmitted in a timely manner.

The following items are common reasons for data rejections by DENSO:

Components

- Part number does not match the part number as requested by DENSO
- Components with 5.1x classified materials are not marked according to ISO 1043 and ISO 11469

Materials

- Material name does not contain the easily identified generic material name (ex: steel, polypropylene, bronze)
- The symbol field is not populated for all plastic (5.x) material classifications
- A minimum of 90% disclosed substance content is not provided for each material (with a maximum of 10% secret or joker substances)

- A suitable application code is not selected for materials containing lead, mercury, cadmium, hexavalent chromium, or PAHs (or their compounds)

These items should be verified prior to submitting data to DENSO via IMDS.

b) PPAP/ISIR Documentation

Suppliers must include documentation that IMDS data submission has been accepted for their parts as part of their PPAP/ISIR package to DENSO. Suppliers should provide the DENSO plant PPAP/ISIR coordinator with documentation showing IMDS acceptance of the part and the associated IMDS ID number.

c) Supplier Information

Table 3 below identifies the information DENSO requires suppliers to maintain with the most current information in IMDS

Table 3: Required Supplier IMDS Information

Field Name	**Description**	**Required/ Optional**
Organization Unit	Only used if company's IMDS account is subdivided into organizational units.	Required
Contact Person	Individual that can answer questions regarding submitted MDS	Required
Telephone No.	Telephone number of contact	Required
Fax No.	Fax number of contact	Required
E-mail Address	E-mail address of contact	Required
Active	For use by Client Managers only.	Required

1. Additional Requirements

Supplier shall also comply with any additional SoC requirements above and beyond IMDS reporting requirements. This may include reporting SoC information in a customer specific format or submitting analytical test values (according to DIS2320 – see Table 1) and test methods to verify data reported in the IMDS process. When applicable, these requests will be issued directly from the plant. Annual SoC conformance testing may be required as determined by your DENSO Quality Representative.

2. Technical Support

For questions regarding DENSO's IMDS reporting requirements, please contact the DENSO SoC Help Desk at SoC.Reporting@na.denso.com.

For IMDS technical assistance, contact the IMDS Service Center. Contact information for the IMDS Service Center can be found at the following website: https://public.mdsystem.com/en/web/imds-public-pages/imds-service-centers

3. Related Documents

- DDS2004 (Password) = z7DnkC
- DIS2320 (Password) = dkss65
- DENSO North America Statement of Environmental & Safety Requirements

These documents can be found at DENSO NA website in Supplier Resource section.

IV.c Non-dimensional Product & Sub-Material Requirements

TOC

Purpose:
The purpose of this section is to identify the minimum environmental and safety requirements that must be followed.
Scope:
This section applies to all non-dimensional and sub-material suppliers who provide chemicals to DENSO.
Link to ISO / MAQMSR:
8.2.2 Determining the requirements for products and services.
Documents related:
N/A

Explanation:
All suppliers are required to abide by the expectations put forth in this policy. Additional requirements may exist and also apply for individual DENSO sites and program teams. Hazardous Materials includes any material or substance that is regulated by any environmental or safety requirement including EPA, OSHA, DOT, etc.
Supplier Responsibilities:
1. Comply with all applicable Federal, Provincial, State and local Environmental, Safety and Hazardous Material Transportation Regulations. 2. Safety Data sheets must be provided for all non-dimensional and sub-material products*. 3. All non-dimensional and sub-material products arriving on site must be properly shipped and labeled*. 4. 100% of formula must be disclosed on the SDS. 5. If the chemical composition information is a trade secret, the supplier can provide information under a non-disclosure agreement between DENSO and the supplier. *Compliance with the updated SDS and labeling requirements of 29 CFR 1910.1200 (which includes global harmonization systems [GHS]) is mandatory for all shipments within the U.S. For shipments to Canada and Mexico, during the transition period to the GHS standard, compliance with the most current regulations in the each country is required.

IV.d Functional Safety ISO26262

TOC

Purpose:
To prevent hazardous events occurring in series production road vehicles caused by electrical and/or electronic (E/E) systems.
Scope:
Applies to suppliers and suppliers' suppliers of parts who designs and electrical and/or electronic (E/E) system parts supplied to DENSO as defined within the ISO26262 Functional Safety standard.
Link to ISO / MAQMSR:
N/A
Documents related:
N/A

Explanation:
DENSO or DENSO's "Customer Requirements" (CR) will define "Functional Safety" audit and assessment requirements to be followed by suppliers or sub-suppliers. ISO26262 Functional Safety standard has been created in order to comply with the needs specific to the application sector of electrical and/or electronic (E/E) systems/parts* for series production road vehicles. *Examples may include but are not limited to: sensor or other input device, programmable electronic element, processing element, actuator, interconnection, power supply. The ISO26262 standard provides detailed industry-specific guidelines for the development phase and after production phase for automotive systems and equipment, whether it is safety-critical or not. Intended to provide confidence in the safety of automotive systems and equipment, ISO26262 covers the complete safety lifecycle including planning, development and integral processes to ensure correctness, control and confidence.
Supplier Responsibilities:
When "Functional Safety" (ISO26262) is specified on the DENSO drawing or DENSO specification, DENSO requires suppliers of electrical and/or electronic (E/E) systems/parts to comply with the following: Section II of this SQAM; Section III of this SQAM; ISO26262 standard. DENSO's Quality Assurance representative will inform suppliers through DENSO drawing/specification and NQAR (refer to section II.a) should compliance with ISO26262 standard be required. • E/E suppliers must manage the delivery of the required evidence of compliance to the ISO26262 standard by DENSO's due date. This includes sub-supplier evidence of compliance where required. 1. E/E suppliers must provide DENSO with evidence of compliance to the ISO26262 standard for the part, including sub-supplier supplied parts. The supplier must make the evidence of compliance available for DENSO to view on-site during audits. • DENSO reserves the right to perform audits and assessments to verify compliance to ISO26262 at the supplier's or sub-supplier's premises. The supplier and/or sub-supplier shall make evidence of compliance available for DENSO to confirm during on-site visits. 2. E/E suppliers and sub-suppliers are to follow the records retention periods defined by DENSO. The Functional Safety records retention periods may be different than those defined in section III.i of this manual. Suppliers are to seek approval from DENSO in advance of the discarding of any quality history records related to DENSO parts.

IV.e Product Cybersecurity (ISO/SAE 21434)

TOC

Purpose:
To assure secure development and operation activities for products requiring cybersecurity risk management activities to offer secure systems and products to the market.
Scope:
Applies to suppliers and suppliers' suppliers of production parts who designs electrical and/or electronic (E/E) system production parts supplied to DENSO as defined within the ISO/SAE 21434 Cybersecurity engineering standard.
Link to ISO / MAQMSR:
N/A
Documents related:
N/A

Explanation:
DENSO or DENSO's "Customer Requirements" (CR) will define "Product Cybersecurity" audit and assessment requirements to be followed by suppliers or sub-suppliers. ISO/SAE 21434 Cybersecurity engineering standard has been created in order to comply with the needs specific to the application sector of electrical and/or electronic (E/E) systems/parts* for series production road vehicles. *Examples may include but are not limited to: sensor or other input device, programmable electronic element, processing element, actuator, interconnection, power supply, software component. The ISO/SAE 21434 standard is intended to provide detailed industry-specific guidelines for cybersecurity risk management of automotive systems and equipment, and covers the complete cybersecurity lifecycle (e.g. planning, development, production, support, end of support) in order to ensure correctness, confidence, control and continual monitoring.
Supplier Responsibilities:
When "Product Cybersecurity" (ISO/SAE 21434) is specified on the DENSO drawing or DENSO specification, DENSO requires suppliers of electrical and/or electronic (E/E) systems/parts to comply with the following: Section II of this SQAM; Section III of this SQAM; ISO/SAE 21434 standard. Additionally, when applicable, comply with type approval requirements related to UNECE WP.29 (ref. R155 and R156). E/E suppliers shall provide evidence of policies and procedures for product security upon request from DENSO supplier quality representative and/or DENSO ISP. This includes sub-supplier evidence where required. • Note: DENSO purchasing group will issue checksheet for supplier and sub-suppliers to complete (e.g. CyberSecurity Management System or "CSMS for Suppliers"). • DENSO ISP will review with the supplier the results of the evaluation of CSMS checksheet and will require improvement actions to be taken by the supplier and sub-suppliers should any non-conformances be identified. DENSO's Quality Assurance representative will inform suppliers through DENSO drawing/specification and NQAR (refer to section II.a) should compliance with ISO/SAE 21434 standard be required. 1. E/E suppliers shall manage the delivery of the required evidence of compliance to the ISO/SAE 21434 standard by DENSO's due date. This includes sub-supplier evidence of compliance where required. 2. E/E suppliers must provide DENSO with evidence of compliance to the ISO/SAE 21434 standard for the production part, including sub-supplier supplied production parts. The supplier must make the evidence of compliance available for DENSO to view.

• DENSO reserves the right to perform [on-site] audits and assessments to verify compliance to ISO/SAE 21434 at the supplier's or sub-supplier's premises. The supplier and/or sub-supplier shall make evidence of compliance available for DENSO to confirm during on-site visits.
3. E/E suppliers and sub-suppliers are to follow the records retention periods defined by DENSO. The Product Cybersecurity records retention periods may be different than those defined in section III.i of this manual. Suppliers are to seek approval from DENSO in advance of the discarding of any quality history records related to DENSO production parts.
4. Currently, DENSO suppliers & sub-suppliers are not authorized to manage product keys.

IV.f Product Security Incident Response Team (P-SIRT)

TOC

Purpose:
To assure information security incidents are managed and mitigated by suppliers and sub-suppliers Security Incident Response Team (SIRT).
Scope:
Applies to security incidents that occurred at suppliers and suppliers' sub-suppliers of development and production parts. Security incidents cover, but are not limited to the following: • Vulnerability of information assets; • Production equipment; • Products under development; • Mass-produced products..
Link to ISO / MAQMSR:
N/A
Documents related:
N/A

Explanation:
Refer to section IV.e. (1) for explanation. Intended to provide confidence in the cybersecurity risk management of automotive systems and equipment, ISO/SAE 21434 covers the complete cybersecurity lifecycle including planning, development and integral processes to ensure correctness, control , confidence and continual monitoring.
Supplier Responsibilities:
DENSO requires suppliers of electrical and/or electronic (E/E) systems/parts to comply with the following: Section II of this SQAM; Section III of this SQAM. DENSO's suppliers and sub-suppliers shall have a cybersecurity policy and system (e.g. process, resources, tool) in place to monitor for weaknesses and vulnerabilities according to the Scope. 1. E/E suppliers shall provide evidence of policies and procedures for security incidents upon request from DENSO supplier quality representative and/or DENSO ISP. This includes sub-supplier evidence where required. Note: DENSO purchasing group will issue checksheet for supplier and sub-suppliers to complete (e.g. CyberSecurity Management System or "CSMS for Suppliers"). • DENSO ISP will review with the supplier the results of the evaluation of CSMS checksheet and will require improvement actions to be taken by the supplier and sub-suppliers should any non-conformances be identified. 2. Should a weakness or a vulnerability impact a supplier's or sub-supplier's product (e.g. during development or during mass production activities or during support period as defined by the cybersecurity lifecycle), DENSO shall be notified within five (5) business days. • Supplier and/or sub-supplier shall notify DENSO's information security promotion (ISP) division at this mailbox: na-denso-psirt@na.denso.com. • Copy [CC:] DENSO's supplier quality representative on the email. • Note: a PGP key can be provided upon request when contacting DENSO's ISP Division. • DENSO and the supplier or sub-supplier shall agree on a remediation plan including but not limited to: i. Communication protocols – response time expectations, contact lists; ii. Investigation process – activities, responsibilities, timeline; iii. Counter-measure or mitigation plan – activities, responsibilities, timeline. 3. E/E suppliers and sub-suppliers are to follow the records retention periods defined by DENSO. The information security incident records retention periods may be different than those defined in section III.i of this manual. Suppliers shall seek approval from DENSO before discarding any quality history records related to DENSO production parts.

IV.g Documented Information

TOC

Purpose:
To ensure that documented information required to satisfy statutory, regulatory, organizational and customer requirements are identified available, suitable, updated, protected, controlled, preserved, and retained.
Scope:
This section applies to suppliers of production parts and raw materials to DENSO.
Link to ISO / MAQMSR:
7.5 Documented information / 7.5.3, 7.5.3.1, 7.5.3.2 Control of documented information / 7.5.2 Creating and updating
Documents related:
N/A

Explanation:
[ISO]: Documented information can vary from one organization to another due to: — the size of organization and its type of activities, processes, products and services. — the complexity of processes and their interactions. — the competence of persons.
Supplier Responsibilities:
[ISO]: The supplier's quality management system shall include: a) documented information required by this manual. b) documented information determined by the organization as being necessary for the effectiveness of the quality management system. **[ISO]: Control of documented information** Documented information required by the quality management system and by ISO 9001 shall be controlled to ensure: a) it is available and suitable for use, where and when it is needed. b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). For the control of documented information, the organization shall address the following activities, as applicable: a) distribution, access, retrieval and use. b) storage and preservation, including preservation of legibility. c) control of changes (e.g. version control). d) retention and disposition. Documented information of external origin determined by the supplier to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled. Documented information retained as evidence of conformity shall be protected from unintended alterations. NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information. **[ISO]: Creating and updating** When creating and updating documented information, the supplier shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number). b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic). c) review and approval for suitability and adequacy.

IV.h Contingency Plans

TOC

Purpose:
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.
Scope:
This section applies to suppliers of products and/or services sent to DENSO.
Link to ISO / MAQMSR:
6.1.2.3 Contingency plans / 6.1.2.1 Risk Analysis
Documents related:
N/A

Explanation:
[ISO]: When planning for the quality management system, the supplier shall consider the internal and external issues and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s). b) enhance desirable effects. c) prevent, or reduce, undesired effects. d) achieve improvement.
Supplier Responsibilities:
[MAQMSR]: The supplier 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 according to risk and impact to DENSO. c) prepare contingency plans for continuity of supply in the event of any of the following, but not limited to: key equipment failures; interruption from externally provided products, processes, and services; recurring natural disasters; fire; pandemics; utility interruptions; cyber-attacks on information technology systems; labor shortages; or infrastructure disruptions. 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 (e.g., simulations, as appropriate); for cybersecurity: testing may include a simulation of a cyber-attack, regular monitoring for specific threats, identification of dependencies and prioritization of vulnerabilities. The testing is appropriate to the risk of associated customer disruption; Note: cybersecurity testing may be managed internally by the organization or subcontracted as appropriate. f) conduct contingency plan reviews (at a minimum annually) using a multidisciplinary team including top management, and update as required. g) document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s). h) include in contingency plans the development and implementation of appropriate employee training and awareness. The contingency plans shall include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed. NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. **[MAQMSR]:** NOTE 1.a The supplier shall retain documented information as evidence of the results of risk analysis. NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

IV.i Supplier Control and Monitoring

TOC

Purpose:
Ensure that externally provided processes, products and services conform to requirements.
Scope:
This section applies to suppliers of products and/or services sent to DENSO.
Link to ISO / MAQMSR:
8.4 Control of external provision of goods and services / 8.4.2 Type and extent of control / 8.4.3 Information for external providers / 8.6.4 Verification and acceptance of conformity of externally provided products and services / 8.4.2.4 Supplier monitoring.
Documents related:
N/A

Explanation:
The supplier shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to DENSO, by determining the controls to be applied to externally provided processes, products, and services when: a) products and services from external providers are intended for incorporation into the organization's own products and services. b) products and services are provided directly to the customer(s) by external providers on behalf of the organization. c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.
Supplier Responsibilities:
[ISO]: The supplier shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The supplier shall retain documented information of these activities and any necessary actions arising from the evaluations. **[ISO]: Type and extent of control** The supplier shall: a) ensure that externally provided processes remain within the control of its quality management system. b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output. c) take into consideration: 1) the potential impact of the externally provided processes, products and services on the supplier's ability to consistently meet customer and applicable statutory and regulatory requirements. 2) the effectiveness of the controls applied by the external provider. d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. **[ISO]: Information for external providers** The supplier shall ensure the adequacy of requirements prior to their communication to the external provider. The supplier shall communicate to external providers its requirements for: a) the processes, products and services to be provided. b) the approval of: 1) products and services. 2) methods, processes and equipment. 3) the release of products and services. c) competence, including any required qualification of persons. d) the external providers' interactions with the organization. e) control and monitoring of the external providers' performance to be applied by the organization; f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

[MAQMSR]: Supplier monitoring
The supplier shall have a documented process and criteria to evaluate supplier performance in order to ensure conformity of externally provided products, processes, and services to internal and external customer requirements.

At a minimum, the following supplier performance indicators shall be monitored:
a) delivered product conformity to requirements.
b) customer disruptions at the receiving plant, including yard holds and stop ships.
c) delivery schedule performance.
If provided by the customer, the organization shall also include the following, as appropriate, in their supplier performance monitoring:
d) special status customer notifications related to quality or delivery issues.
e) dealer returns, warranty, field actions, and recalls.

[MAQMSR]: Verification and acceptance of conformity of externally provided products and services

The supplier shall have a process to ensure the quality of externally provided processes, products, and services utilizing one or more of the following methods:
a) receipt and evaluation of statistical data provided by the supplier to the organization.
b) receiving inspection and/or testing, such as sampling based on performance.
c) second -party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements.
d) part evaluation by a designated laboratory.
e) another method agreed with the customer.

V. Additional Information

V. a. Glossary

TOC

Item	Definition
Automotive Industry Action Group (AIAG)	A coalition of automotive manufacturers that produce standardized manuals to follow to help Suppliers meet the needs of the automotive industry. Examples: Quality Systems Requirements- Potential Failure Mode and Effects Analysis (FMEA), Measurement Systems Analysis (MSA), Statistical Process Control (SPC). AIAG manuals: order at: **https://www.aiag.org/quality/automotive-core-tools**
AIAG Compliance Connect Spreadsheet/IMDS	Forms used to report product structure, material, substance, and recyclability information for parts and materials supplied to DENSO. This is per EU directive and OEM requirements.
Blank Forms	These are blank copies of *DENSO* forms that are to be used by Suppliers to meet the submission requirements of DENSO.
Boundary Sample	Boundary samples show the acceptable visual limit of a part/ material. Boundary samples are used in conjunction with the DENSO Supplier Inspection Standard and are developed with DENSO support.
Capability Index (Cpk)	A measure of process variation and centering relative to the specification range and target.
Control Plan (also check AIAG manual 'APQP')	The DENSO Supplier Control Plan is used by the supplier to indicate the critical product characteristics, process steps, Quality Assurance check items (with their frequencies), SPC reporting methods, process capability, and Gage R & R studies that relate to the parts/ material which are supplied to DENSO. It is comprehensive and includes all important information from Receiving Inspection through Packaging.
Critical Control Characteristics	Characteristics of a product or process either designated by the customer or selected by the supplier through knowledge of the product or process. Excessive variation may affect product safety, compliance with government regulations, fit, function, appearance or quality of subsequent operations.
DENSO	Within this manual the name "DENSO" shall refer to DENSO manufacturing companies in North America:
Deviation Request/ Reply	This form is submitted by the supplier to DENSO when the supplier wants DENSO to accept products, parts, components, or materials that do not meet drawings and/ or specifications. This form is submitted for all non-conformances from Initial Samples through Mass Production.
Early stage control plan for production ramp-up.	This form contains the supplier's plans to help ensure that their production processes are stabilized as soon as possible after start of production. It focuses on early detection of potential problems and how countermeasures are to be implemented and reviewed by supplier management to help ensure a successful start-up of production.

Field Corrective Action Request (FCAR)	This form is sent to the supplier by DENSO when nonconforming parts/ materials from the supplier have been detected at DENSO. It is also used to reply to the information sent by the supplier on the G8D Sheet. DENSO will either approve the actions taken by the supplier or request that further actions be taken before the Corrective Action is closed out.
Final Approval Request	This form is submitted by the supplier to DENSO once they have completed all the requirements stated on the DENSO Notification of Quality Assurance Requirements (NQAR). Your DENSO Quality Representative will review the form and the submissions that have been given by the supplier and if everything is satisfactory, will sign approval on the form and forward a copy to the supplier for their records.
Gage Repeatability and Reproducibility Study (GR&R) (also check AIAG manual 'MSA')	This study is done by the supplier to evaluate the amount of measurement error associated with a particular gage. The GR&R will demonstrate whether there is enough of a confidence level in the gage for it to be used to evaluate parts/ materials that are to be supplied to DENSO.
Global 8D (G8D) Sheet	This form is completed by the supplier in response to a DENSO Supplier Quality Failure Notice that has been issued as the result of nonconforming parts/ material from the supplier having been detected at DENSO. It documents the supplier's effort to contain the nonconformance, detect the root cause, and implement countermeasures to prevent its recurrence.
Initial Sample Inspection Report (ISIR)	The supplier sends the ISIR to DENSO along with representative samples of the parts/ materials that it will be submitting to DENSO. It is used to show initial stage confirmation of the parts/ materials produced on mass production tooling to DENSO drawings and specifications.
Lot Information and Traceability	Supplier utilizes this form to communicate important information about how their product is packaged and what is their system for traceability
Master Sample	Master samples show acceptable visual final characteristics. Master samples are used in conjunction with the DENSO Supplier Inspection Standard and are developed with DENSO support.
Management review	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with strategic direction of the organization.
Notification of Quality Assurance Requirements (NQAR)	This form is used by DENSO to convey to the Supplier DENSO SQAM requirements/submissions and due dates. Critical control items for DENSO's process/product are also included on the form.
OEM; Original Equipment Manufacturer	Refers to a company producing a final product sold as their brand (includes but is not limited to auto-makers)
Part Corrective Action Request (PCAR)	This form is sent to the supplier by DENSO when nonconforming parts/ materials from the supplier have been detected at DENSO. It is also used to reply to the information sent by the supplier on the G8D Sheet. DENSO will either approve the actions taken by the supplier or request that further actions be taken before the Corrective Action is closed out.

Process Change Request/ Reply	This form is used to document a supplier's request to make a change to the process that they use to produce a product for DENSO. It also notes DENSO's response to the request by the supplier.
Process Capability Studies (also check AIAG manual 'Statistical Process Control-SPC')	Process capability studies are carried out in order to obtain information on the inherent variation that exists within a process that is under statistical control, in order to reduce the spread of variation to less than the tolerances stated within the product specification.
Quality Assurance Schedule (QAS)	QAS should include the following items: Component Build and Ship Schedule; Production Process Development; Quality System Development; Material, ISIR, & Appearance Evaluations
Quality Failure Answer Sheet (QFAS)	This form is sent to the supplier by DENSO when nonconforming parts/ materials from the supplier have been detected at DENSO. It is used to reply to the information sent by the supplier on the G8D Sheet. DENSO will either approve the actions taken by the supplier or request that further actions be taken before the Quality Failure Notice is closed out.
Quality Failure Notice (QFN)	This form is sent to the supplier by DENSO when nonconforming parts/ materials from the supplier have been detected at DENSO. It is also used to reply to the information sent by the supplier on the G8D Sheet. DENSO will either approve the actions taken by the supplier or request that further actions be taken before the Quality Failure Notice is closed out.
Quality Management System	Strategic decision for the organization that can help to improve its overall performance and provide a sound basis for suitable development of initiatives.
Statutory and regulatory requirements	Statutory and regulatory requirements referred to the requirements, notices, directives, or applicable laws that were issued by government; regulatory is referred to rules to supplement laws that businesses must follow.
Supplier QA Contacts List	This list is submitted to DENSO by the supplier to identify critical contacts for DENSO at the supplier.
Tooling Progress Report (TPR)	A TPR must be prepared for all new dies, molds, equipment, jigs, custom gages, and fixtures. This schedule must include all activities from design through mass production. This schedule must also include sub-supplier tooling schedules.

V.b. Revision Log

TOC

Date	Section/ Page	Deletion/ Addition/ Change	Description of Change
6/23/2010	020	Change	020b VAVE Proposal form updated
6/23/2010	020	Change	020a Process Change Request Form updated
6/23/2010	006	Change	006 NQAR form updated
7/9/2010	007	Change	Section 007 protected document password info
7/9/2010	007	Addition	Form 007-password reference file
2/3/2011	006	Change	Unified the NQAR Form updated, and removed all language referencing the "Supplier Shipping Inspection Standard" form.
10/20/2011	012	Change	Form 012 ISIR had DMMI Sample Data Sheet added as separate tab
10/20/2011	017	Addition	New Language to the bottom of table 2, "Supplier adherence responsibilities table 2 (DNMX)"
10/20/2011	023	Addition	Language explaining DCAP (Defect Containment Assurance Program) was added to section
04/01/2015	All	Change	New numbering system for Table of Contents.
04/01/2015	All	Change	Changed form numbers to match new Table of Contents formatting.
04/01/2015	II.k	New	Add guidelines for capacity verification and Run @ Rate due to customer requirements and past delivery problems caused by insufficient part availability. Reference new Capacity Verification Form
04/01/2015	IV. e	New	Add new section of requirements requiring compliance to ISO 26262 Functional Safety guidelines.
04/01/2015	IV. c	Change	Update requirements for SoC including requiring compliance to DDS 2004.
04/01/2015	IV. b	New	Add requirements of Conflict Mineral usage per Frank Dodd act from 2010.
04/01/2015	IV. d	New	EHS is attached both as a stand alone section entitled "Chemical Compliance" and also rolled into a renamed "Substance of Concern (SoC) and Environmental & Safety Requirements" section which is attached as a red-line version.
04/01/2015	I. b	New	Add safety related requirements for raw material suppliers. Made TOC Standard.
04/01/2015	IV. a	Change	Slight re-wording of purpose for ease of supplier understanding. Clarification of expectation/content of "Material Specification" which is called out in the supplier expectations.

			Clarify reference of ECR/PCR to match Section III.d (Process & Design Change Requests).
04/01/2015	III. d	Change	Need to align material related changes to DENSO's ESC requirements. Clarify explanation: Change of material suppliers should not be considered only a process change, but a design change Clarify process change definitions (as related to material) Consider inclusion of shifting from PCR to ECR (Engineering change) or DCR (design change request). This is not spelled out Review Table to identify which items may be Design Change (not just Process Change)
04/01/2015	I. a	Change	Updates to Introduction to SQAM Requires compliance to CSR's outside scope of ISO/TS
04/01/2015	II. c	New	Add requirements regarding process auditing and submission of process audit self-assessment sheets.
04/01/2015	II. c	New	Add special process requirements
09/01/2016	Forms	Change	Mass Production Readiness form (updated)
09/01/2016	II. i	Change	Mass Production Readiness Audit
09/01/2016	Forms	New	New Supplier Assessment form (standard for NA)
09/01/2016	I. f	New	New Supplier Assessment
09/01/2016	I. g	New	Continuous Improvement
09/01/2016	I. h	New	Review of Product Requirements with Supplier
09/01/2016	II. c	New	Critical Control Designation
09/01/2016	I. b	New	Confidentiality
09/01/2016	III. h	New	Record Retention
09/01/2016	III. g	New	Quality Escalation/Reaction Plan
09/01/2016	III. g	Change	Clarify Charge backs. Section Reorganized
09/01/2016	III. b	Change	Clarify Deviation Approval
09/01/2016	III. c	Change	Boundary, Master, Material Samples
09/01/2016	III. d	Change	Process/Design Change Request
09/01/2016	III. e	Change	Rework Procedure
09/01/2016	IV. a	Change	Materials change
09/01/2016	Forms	Change	Update TAC Form for Process Change
08/01/2017	I. a /p4	Change	Update reference to IATF 16949 instead of ISO/TS 16949
08/01/2017	I. f /p12	Change	Typo correction

08/01/2017	I. g /p13	Change	Add FMEA to the continuous improvement examples.
08/01/2017	II. d /p23	Change	Add IATF 16949 to the references for control plan.
08/01/2017	II. f /p26	Change	Add number of cavities that need to be measured for ISIR.
08/01/2017	IV. c /p62	Change	Modify password for DDS2004.
08/01/2017	IV. c /p61	New	Add contact info for SoC technical support
11/17/2017	I. a /p4	Change	Add expectation to pursue IATF as ultimate goal. Add expectation to cascade applicable requirements down the supply chain to the point of manufacture.
3/19/2020	All	Change	All sections were changed except for I.b, I.d, I.e, I.g, II.a, II.e, II.j, II.l, II.m, III.b and IV.d. Refer to SQAM site for 2019-2020 NA QE team revision document folder.
3/19/2020	II.d,f	New	Added MSA and PFMEA per AIAG and VDA guidelines
06/14/2022	II.b.	New	Addition; OEM & DENSO Special Requirements
06/14/2022	II.b.5	New	Addition; Cascading of OEM & DENSO requirements
06/14/2022	II.d.3	New	Addition; 1) New Production line PFMEA method, 2) mandatory risk reduction, 3) additional risk mgmt
06/14/2022	II.d.7	New	Addition; content for PFMEA re-evaluation
06/14/2022	II.d.9	New	Addition; Process changes for S>7
06/14/2022	II.d.10	New	Addition; Supp Resp.; Risk Mgmt applied in case of outflow.
06/14/2022	II.d.	New	Addition; Supplier Resonsibility, items 1-10.
06/14/2022	II.d.	New	Additions; Process Performance & Risk Mgmt
06/14/2022	II.n.	New	Addition; Production Quality Evidence
06/14/2022	III.g.1.a	New	Additions; S and D failure ranks
06/14/2022	III.g.1.b	New	Addition; S rank
06/14/2022	I.d. & III.g	New	Addition; DENSO role in Corrective Action activity.
06/14/2022	V	New	Addition; OEM definition.

Revision date: 8/M/2024

Section	Title	Description of change
I.a	Introduction to the DENSO Supplier Quality Assurance Manual (SQAM)	Addition; Examples of production parts.
I.b	DENSO Site Safety and Security Guidelines for Visiting Suppliers	Change: Standard OSHA was replaced for ANSI 287.
I.b	DENSO Site Safety and Security Guidelines for Visiting Suppliers	Addition; Convey additional requirements.

I.d	Fundamental requirements	Addition; New section "Fundamental requirements" according to ISO & MAQMSR.
I.e	Understanding the organization and it's context	Addition; New section "Understanding the organization and it's context" according to ISO & MAQMSR.
I.f	Quality Management System	Addition; New section "Quality Management System" according to ISO & MAQMSR.
I.g	Management Review	Addition; New section "Management Review" according to ISO & MAQMSR.
I.h	Organizational roles, responsibilities and authorities	Addition; New section "Organizational roles, responsibilities and authorities" according to ISO & MAQMSR.
I.i	Internal Audits	Addition; New section "Internal Audits" according to ISO & MAQMSR.
I.j	Supplier Quality Performance Monitoring System	Addition; 1. Indicators to monitor supplier performance. 2. Supplier responsibilities according to ISO requirements. 3. Corrective actions within supplier responsibilities.
I.j	Supplier Quality Performance Monitoring System	Change: Explanation of supplier performance updated.
I.k	Supplier Quality Assurance Contacts	Addition; ISO requirement within supplier responsibilities.
I.l	New Supplier Evaluation	Addition; Word "production" (as reference of production parts) was included within scope portion.
I.l	New Supplier Evaluation	Addition; point #5 within supplier responsibilities.
I.l	New Supplier Evaluation	Change: Within supplier evaluation, regarding QE evaluation (point #4) was updated.
I.m	Continuous Improvement	Addition; update within supplier responsibilities, ISO requirement was added.
I.n	Review of Products and Services Requirements with Supplier	Addition; ISO & MAQMSR requirements within explanation and supplier responsibilities portions.
II.a	NQAR	Addition; ISO requirements within explanation portion.
II.b	New Product Development Planning	Addition; Tooling requirements within supplier responsibilities portion.
II.c	Process Capability Requirement	Addition; 1. MAQMSR requirements within supplier responsibilities portion. 2. Rubber was added in special process portion. 3. Details on CPK values.
II.d	PFMEA	Addition; 1. MAQMSR requirements within explanation and supplier responsibilities portions. 2. Medium severity ranks within supplier responsibilities. 3. Error proofing requirements (from MAQMSR) added within supplier responsibilities.
II.f	MSA	Addition; ISO & MAQMSR requirements within supplier responsibilities.

II.g	Control Plans	Addition; 1. Conformance requirements within supplier responsibilities portion. 2. MAQMSR requirements within supplier responsibilities.
II.h	PPAP Initial Sample Submission	Addition; 1. Samples details within explanation and supplier responsibilities portions. 2. MAQMSR requirements within supplier responsibilities portion.
II.i	Lot Identification and Traceability	Change: 1. Within explanation portion, definition of "Traceability and "Identification" were updated. 2. Within supplier responsibilities portion, requirements for traceability and identification were updated.
II.j	Design and development process	Addition; New section "Design and development process" according to ISO & MAQMSR.
II.k	Early Stage Control for Mass Production Ramp-Up	Change: Timing of submissions (point b)
II.l	Mass Production Readiness Review	Addition; ISO requirement within supplier responsibilities portion.
III.a	Product Shipment Notification – Stratification Control Process	Addition; 1. Supplier adherence for DNMX and DMAT processes within scope portion. 2. ISO requirement within explanation portion. 3. Supplier adherence responsibilities table for DMAT.
III.b	Deviation Request Reply	Addition; MAQMSR requirements within supplier responsibilities.
III.d	Control of changes	Addition; New section "Control of changes" according to ISO & MAQMSR.
III.f	Rework and Repair Procedure	Addition; MAQMSR requirements within supplier responsibilities portion.
III.h	Non-Conforming Product Communication and Corrective Action Process	Addition; ISO & MAQMSR requirements within explanation and supplier responsibilities.
IV.e	Product Cybersecurity (ISO/SAE 21434)	Addition; New section "Product Cybersecurity (ISO/SAE 21434)".
IV.f	Product Security Incident Response Team (P-SIRT)	Addition; New section "Product Security Incident Response Team (P-SIRT)".
IV.g	Documented Information	Addition; New section "Documented Information" according to ISO & MAQMSR.
IV.h	Contingency Plans	Addition; New section "Contingency plans" according to ISO & MAQMSR.
IV.i	Supplier Control and Monitoring	Addition; New section "Supplier Control and Monitoring" according to ISO & MAQMSR.
I.n	Review of products and services requirements with supplier	Change: Title, "and services" was added due to alignment with ISO & MAQMSR requirements.

II.g	Control Plans	Change: Title, Plans instead of plan, due to alignment with ISO & MAQMSR requirements.
III.f	Rework and repair procedure	Change: Title, "and repair" was added due to alignment with ISO & MAQMSR requirements.
All sections	-	Change: Link to ISO & MAQMSR section was added. Document related portion was added.

V.c. Bibliography

TOC

DN SQAM Table of Contents	Source of content
I. Introduction and General Information	
a. Introduction to the DENSO Supplier Quality Assurance Manual (SQAM)	DENSO Unique Requirement
b. DENSO Site Safety and Security Guidelines for Visiting Suppliers	ISO 14001 Environmental Management Systems ANSI Z87 Safety Glasses Standard
c. Supplier Use of Workers for Temporary Service at DENSO	DENSO Unique Requirement
d. Fundamental requirements	ISO 9001:2015 & MAQMSR
e. Understanding the organization and it's context	ISO 9001:2015
f. Quality Management Systems	ISO 9001:2015
g. Management Review	ISO 9001:2015 & MAQMSR
h. Organizational roles, responsibilities and authorities	ISO 9001:2015 & MAQMSR
i. Internal Audits	ISO 9001:2015 & MAQMSR
j. Supplier Quality Performance Monitoring System	ISO 9001:2015 & MAQMSR
k. Supplier Quality Assurance Contacts	ISO 9001:2015
l. New Supplier Evaluation	DENSO Unique Requirement
m. Continuous Improvement	ISO 9001:2015
n. Review of Products and Services Requirements with Supplier	ISO 9001:2015 & MAQMSR
II. Quality Assurance in Pre-Mass Production	
a. NQAR	ISO 9001:2015
b. New Product Development Planning	ISO 9001:2015
c. Process Capability Requirements	MAQMSR
d. PFMEA	MAQMSR
e. QA Network	DENSO Unique Requirement
f. MSA	ISO 9001:2015 & MAQMSR
g. Control Plans (ANNEX A incorporated)	MAQMSR
h. PPAP Initial Sample Submission	MAQMSR
i. Lot Identification and Traceability	ISO 9001:2015 & MAQMSR
j. Design and development process	ISO 9001:2015
k. Early Stage Control for Mass Production Ramp-up	ISO 9001:2015
l. Mass Production Readiness Review	ISO 9001:2015
m. Mass Production Approval	MAQMSR
n. Supplier Capacity Verification	IATF 16949:2016
o. Production Quality Evidence	ISO 9001:2015
III. Quality Assurance Trials and Mass Production	
a. Product Shipment Notification - Stratification Control Process	ISO 9001:2015 & MAQMSR
b. Deviation Request/Reply	MAQMSR
c. Boundary, Master and Material Samples	IATF 16949:2016

d. Control of changes	ISO 9001:2015 & MAQMSR
e. Process and Design Change Request	ISO 9001:2015 & MAQMSR
f. Rework and Repair Procedure	MAQMSR
g. Trouble Shooting and Abnormalities	ISO 9001:2015
h. Non-Conforming Product Communication and Corrective Action Process	ISO 9001:2015 & MAQMSR
i. Record Retention	IATF 16949:2016
IV. Other Requirements	
a. Special Section for Materials Only Suppliers	ISO 9001:2015
b. Substance of Concern (SOC) Requirements	ISO 9001:2015
c. Non-Dimensional Product and Sub-Material Requirements	ISO 9001:2015
d. Functional Safety ISO26262	ISO 26262
e. Product Cybersecurity (ISO/SAE 21434)	ISO/SAE 21434
f. Product Security Incident Response Team (P-SIRT)	ISO/SAE 21434
g. Documented information	ISO 9001:2015
h. Contingency Plans	ISO 9001:2015& MAQMSR
i. Supplier Control and Monitoring	ISO 9001:2015 & MAQMSR