8.4 - Control of externally provided processes, products and services (8.4.1 General)

8.4 - Control of externally provided processes, products and services (8.4.1 General)

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine 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;

8.4 - Control of externally provided processes, products and services (8.4.1 General)

c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization 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 organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

Explanation

There is an increased focus on external providers and external providers to include those directly supplying to customer on organization behalf

Documentation Requirement

Documented Information – Mentioned

E.g. 1 – List of External provider

E.g. 2 – Supplier Evaluation sheet

How to implement this clause?

Step 1 – Identify the list of external provided products, process and services

Step 2 – Define the criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers

8.4.1.1 General - supplemental

8.4.1.1 General - supplemental

The organization shall include all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services.

Explanation

The former NOTE about purchased product has been elevated into a requirement.

Documentation Requirement

Documented Information – Not Mentioned

E.g. 1 – list of suppliers for sub-assembly, sorting, rework and calibration service provider for organization

How to implement this clause?

Step 1 – Identify the list of suppliers for sub-assembly, sorting, rework and calibration service provider for organization

Step 2 – Define the criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers

8.4.1.2 - Supplier selection process

8.4.1.2 - Supplier selection process

The organization shall have a documented supplier selection process. The selection process shall include:

a) an assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers;
b) relevant quality and delivery performance’s
c) an evaluation of the supplier's quality management system;
d) multidisciplinary decision making; and

8.4.1.2 - Supplier selection process

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

Explanation

There is a very detail requirement for new supplier selection

Any new supplier selection goes beyond QMS audits and includes aspects such risk to product conformity and uninterrupted supply, relevant quality and delivery performance and evaluation of the suppliers' quality management system.

Documentation Requirement

Documented Process - Mentioned

Documented Information – Required

E.g. 1 – Supplier Audit Report / Action Plan

How to implement this clause?

Step 1 – Identify the list of suppliers for sub-assembly, sorting, rework and calibration service provider for organization

Step 2 – Implement the supplier selection through audit check sheet

8.4.1.3 - Customer-directed sources (also known as “Directed–Buy”)

8.4.1.3 - Customer-directed sources (also known as “Directed–Buy”)

When specified by the customer, the organization shall purchase products, materials, or services from customer-directed sources.

All requirements of Section 8.4 (except the requirements in Section 8.4.1.2) are applicable to the organization’s control of customer-directed sources unless specific requirements are otherwise defined by the contract between the organization and the customer.

Explanation

This section gives clarity for the organization's responsibilities for customer directed sources.

Documentation Requirement

Documented Information – Not Mentioned

How to implement this clause?

Step 1 - Make a list of customer directed sources (if any & ensure proof of customer directed sources in the form of MOM / E-Mail)

Step 2 – Ensure monitoring of customer directed sources (the only exception could be initial supplier selection audits / evidence)

8.4.2 - Type and extent of control

8.4.2 - Type and extent of control

The organization 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 its customers.

The organization 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:

8.4.2 - Type and extent of control

1) the potential impact of the externally provided processes, products and services on the organization'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.

Explanation

This section gives clarity for the organization's responsibilities for customer directed sources.

Documentation Requirement

Documented Information – Not Mentioned

How to implement this clause?

The organization to define and verify control for purchased product.

The controls for example might include Receiving Inspection, Test Certificate, supplier audits, etc.

8.4.2.1 Type and extent of control - Supplemental

8.4.2.1 Type and extent of control - Supplemental

The organization shall have a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal (organizational) and external customer requirements.
The process shall include the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks.

Where characteristics or components “pass through” the organization’s quality management system without validation or controls, the organization shall ensure that the appropriate controls are in place at the point of manufacture

Explanation

The changes further strengthened the requirement for control of outsourced processes considering the assessment of the risk

Example - Supplier audit frequency is annual. If consecutive 2 month customer complaint because of suppler or worst supplier rating for 3 months, than frequency of supplier audit to be changed to quarterly.

This is just one example; there could be other control to escalate like tight sampling inspection, supplier third party inspection, audit, etc.

Documentation Requirement

Documented Information – Not Mentioned

How to implement this clause?

Step 1 - Identify the risk of supplier for changes further strengthened the requirement

Step 2- Monitor the action and implement the same when ever required

8.4.2.2 - Statutory and regulatory requirements

8.4.2.2 - Statutory and regulatory requirements

The organization 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 the customer defines special controls for the certain products with statutory and regulatory requirements, the organization shall ensure they are implemented and maintained as defined, including at suppliers.

Explanation

This clause further strengthened the applicability of statutory and regulatory requirements.

Documentation Requirement

Documented Information – Not Mentioned

E.g. 1 - Identification of statutory and Regulatory requirements for BOP & RM

How to implement this clause?

Step 1 - Identify any statutory and regulatory requirements related to product being bought

Step 2 - Ensure study of customer specific requirements for any special controls related to statutory and regulatory requirements.

Step 3 – Update Identification of statutory & regulatory requirements with communication to supplier (as per the example format given in the resources)

8.4.2.3 Supplier quality management system development

8.4.2.3 Supplier quality management system development

The organization shall require their suppliers of automotive products and services to develop, implement, and improve a quality management system (QMS) with the ultimate objective of eligible organization becoming certified to this Automotive QMS Standard.
Using a risk based model, the organization shall define a minimum acceptance level of QMS development and a target QMS development level for each supplier.
~~Certified to ISO 9001, unless otherwise~~ unless otherwise authorized by the customer ~~[e.g, item a) below]~~, a QMS certified to ISO 9001 is the minimum acceptance 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 :
~~with the ultimate objective of becoming certified to this Automotive QMS Standard.~~
~~Unless otherwise specified by the customer, the following sequence should be applied to achieve this requirement:~~

8.4.2.3 Supplier quality management system development

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 (International Accreditation Forum Multilateral Recognition Arrangement) 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 [MAQMSRJ or equivalent) through second-party audits;

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

8.4.2.3 Supplier quality management system development

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

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

Explanation

There is now a 4-step development process for supplier. This approach supports the risk-based thinking approach.

Also, there is a clarification of acceptable third-party certification bodies.

Documentation Requirement

Documented Information – Not Mentioned

E.g. 1 - Evidence of supplier ISO certificate

E.g.2 - Supplier audit plan

How to implement this clause?

Step 1 - Identify the current level / certification status of each suppliers

Step 2 – Based on the risk analysis, identify the desired level of QMS development as required

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

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

The organization shall require their suppliers of automotive product-related software, or automotive products with embedded software, to implement and maintain a process for software quality assurance for their products.

A software development assessment methodology 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.

Explanation

The requirement for software capability assessment is cascaded down to suppliers

Documentation Requirement

Documented Information – Not Mentioned

How to implement this clause?

Step 1 - Identify if any supplier supplying product with embedded software.

Step 2 – If Yes, ensure documented information for a software development capability self-assessment

8.4.2.4 - Supplier Monitoring

8.4.2.4 - Supplier Monitoring

The organization 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;
d) number of occurrences of premium freight.
If provided by the customer, the organization shall also include the following, as appropriate, in their supplier performance monitoring:
e) special status customer notifications related to quality or delivery issues;
f) dealer returns, warranty, field actions, and recalls.

Explanation

Strengthened the requirements for supplier monitoring

Documentation Requirement

Documented Process – Mentioned

Documented Information – Not Mentioned

E.g. - Monitoring of supplier indicators

How to implement this clause?

Step 1 –Identify the evaluation criteria for suppliers

Step 2 – Ensure monitoring of supplier performance on identified parameters

8.4.2.4.1 Second-party audits

8.4.2.4.1 Second-party audits

The organization shall include a second-party audit process in their supplier management approach.

Second-party audits may be used for the following:
a) supplier risk assessement;
b) supplier monitoring;
c) supplier QMS development;
d) product audits;
e) process audits.

8.4.2.4.1 Second-party audits

Based on a risk analysis, including product safety/regulatory requirements, performance of the supplier, and QMS certification level, at a minimum, the organization shall document the criteria for determining the need, type, frequency, and scope of second-party audits.

The organization shall retain records of the second-party audit reports.
If the scope of the second-party audit is to assess the supplier's quality management system, then the approach shall be consistent with the automotive process approach.
NOTE Guidance can be found in the IATF Auditor Guide, ISO 17021, and ISO 19011.

Explanation

The organization's criteria for determining the need, type, frequency, and scope of second-party audits must be based on a risk analysis.

Documentation Requirement

Documented Information – Mentioned

E.g.1 - Supplier audit plan,

E.g.2 - supplier audit reports

How to implement this clause?

Step 1 – Establish the supplier audit plan frequency and type of audit based on risk analysis

Step 2 – Carry out audit as per the supplier audit plan with the supplier audit check sheet

Step 3 – Ensure monitoring and closure of audit points on timely basis

8.4.2.5 Supplier development

8.4.2.5 Supplier development

The organization shall determine the priority, type, extent, and timing of required supplier development actions for its active suppliers. Determination inputs shall include but are not limited to the following:
a) performance issues identified through supplier monitoring (see Section 8.4.2.4);
b) second-party audit findings (see Section 8.4.2.4.1);
c) third-party quality management system certification status;
d) risk analysis.

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

Explanation

There is more emphasis on performance-based supplier development actions.

Documentation Requirement

Documented Information – Not Mentioned

How to implement this clause?

Step 1 – Identify the supplier for development activities based on the performance and issues

Step 2 – Carry out development activities (Audits, Cluster Programme, etc) for continual improvements

8.4.3 - Information for external providers

8.4.3 - Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.
The organization 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.

Explanation

This clause emphasizes more specific requirements through P.O & terms, inspection agreement, supplier manuals, etc. MOM, etc.

Documentation Requirement

Documented Information – Not Mentioned

E.g.- P.O & supplier terms

How to implement this clause?

Step 1 - Ensure that the all requirements communicated to supplier

Step 2 – Follow and monitor the requirements are implemented at supplier end

8.4.3.1 Information for external providers - supplemental

8.4.3.1 Information for external providers - supplemental

The organization shall pass down all applicable statutory and regulatory requirements and special product and process characteristics to their suppliers and require the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.

Explanation

This clause requires organization to pass down key information throughout the supply chain. This can be through drawings, P.O, inspection standard, etc.

Documentation Requirement

Documented Information – Not Mentioned

How to implement this clause?

Step 1 - Ensure that the all the relevant and applicable statutory and regulatory requirements / special characteristics given to supplier.