



Chapter 24. Purchasing and Control of External Providers

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0) Introduction

This is another long chapter. Purchasing and outsourcing are becoming very important in manufacturing and therefore deserve more attention. This area has seen the inclusion of many new clauses. IATF auditors tend to spend a lot of time here, besides on the production floor. A good understanding of the requirement is therefore recommended.

1) 8.4, 8.4.1 Control of Externally Provided processes, products and services (ISO9001)

(Clause Description-Paraphrase)

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; (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

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.4.1 Purchasing Process, in the previous version ISO/TS16949.



- In the old version, it requires the organization to purchase conforming to requirements. Controls on the supplier and purchased products shall depend on impact to quality. Supplier's selection is on their ability to supply products to requirement.
- It also required Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained
- All the previous requirements are retained in the new clause, and expanded.
- The new clause expands the scope the various type of external provided products and services that need control. See a) to c)
- Extend of control depending on impact somehow has been removed.
- Note that there is a change of terminology: suppliers are now referred to as "external providers"

(Compliance best practice)

8.4, 8.4.1 Control of Externally Provided processes, products and services

1. This requirements is for ISO9001.
2. To comply with ISO9001, 2 important documents are (a) approved supplier list, (b) re-evaluation results. A procedure on supplier selection will make full compliance.
3. There is also a lot of latitude allowed for ISO9001, as to what suppliers to control and how to control.
4. As this discussion is written for automotive, follow the next clause 8.4.1.1 and other IATF clauses below, for compliance

2) 8.4.1.1 General-supplemental (IATF16949)

(Clause Description-Paraphrase)

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

(Highlights of the clause)

- (Ref to old Standards). This was part of the old 7.4.1, now elevated to be a clause.
- The Clause compliance is straightforward and does not need much clarification.
- Total compliance will include 8.4.1 and 8.4.1.1. The latter spells out what areas can be outsourced or purchased.
- Take note that calibration shall be managed like materials and services.

(Compliance best practice)

8.4.1.1 General-supplemental

1. The clause spells out the controls you must have on external providers, including outsourcing
2. Your approved supplier list (**Exhibit 24-1**) shall have all suppliers involved for: direct materials, indirect materials, critical services e.g. calibration, transportation and maintenance services for critical machines.
3. With the new version, there are a lot emphasis on safety, and statutory and regulatory compliances.

4. *You should start to grade your suppliers to meet the requirements of the new IATF version.. The recommended grading is: A: Safety-Related, B: Regulatory-Related, C: Quality-Critical, D: Normal Purchases.*

3) 8.4.1.2 Supplier Selection Process (IATF16949)

(Clause Description-Paraphrase)

The organization shall include all products and services that affect customer requirements such as subassembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services. 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;
- c) an evaluation of the supplier's quality management system;
- d) multidisciplinary decision making; and
- e) an assessment of software development capabilities, if applicable.

Other supplier selection criteria that should be considered include the following: volume of automotive business (absolute and as a percentage of total business); — financial stability;

- purchased product, material, or service complexity;
- required technology (product or process);
- adequacy of available resources (e.g., people, infrastructure);
- design and development capabilities (including project management); manufacturing capability;
- change management process;
- business continuity planning (e.g., disaster preparedness, contingency planning); logistics process;
- customer service.

(Highlights of the clause)

- (Ref to old Standards). Selection of suppliers was part of 7.4.1 in the old version of ISO9001/IATF16949. It has been elevated to be a clause on its own.
- The Clause although long, is quite straightforward and does not need much clarification.
- There are 2 sets of requirements. Point a) to e) are 'shall' items and must be available for selection decision.
- The second part of criteria are "should" items. It is in your discretion whether to obtain those information. A point to highlight is you must have a documented criteria for supplier selection

(Compliance best practice)

8.4.1.2 Supplier Selection Process

1. *You should use a supplier application form, or equivalent, to process supplier selection. All the requirements can be listed down in the form. This can be filled by supplier and returned. It can then be verified by your team, and recommendations made for management approval. See **Exhibit 24-2** for a specimen.*
2. *For suppliers producing parts to your specs, onsite audits shall be part of the evaluation. The onsite audit report shall be attached to the documents for decision making.*
3. *For suppliers who are just distributors for some well-known manufacturers e.g. resins from Dupont, onsite audit may not be required. Product specs and manufacturer's ISO9001 cert should suffice.*

4. *You now need to include in your documentation how the decisions are made (e.g. on point system).*

4) 8.4.1.3 Customer-directed sources (also known as “direct-buy” (IATF16949)

(Clause Description-Paraphrase)

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 IATF 16949, Section 8.4.1.2) are applicable to the organization's control of customer-directed sources unless specific agreements are otherwise defined by the contract between the organization and the customer.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.4.1.3. Customer-approved sources, in the previous version of ISO/TS16949.
- The requirements were retained in concept with different wordings
- The requirement now is “comply to customer specification on suppliers, if directed so, control of the directed- supplier is still organization's , unless there is an agreement between you and the customer stating otherwise”
- Note that although the supplier is nominated by the customer, the responsibility of ensuring their performance still belong to the organization

(Compliance best practice)

8.4.1.3 Customer-directed sources (also known as “direct-buy”)

1. *This type of suppliers are nominated by customer and you need to abide*
2. *But take note that the responsibility to ensure quality and service is still yours. So they have to be managed just like any other type of suppliers*
3. *You need to provide evidence that a supplier is nominated, if there are no selection records. Email records, vendor meeting, project meeting etc should be retained. Otherwise you risk getting a finding*

5) 8.4.2 Type of extend of control (ISO9001)

(Clause Description-Paraphrase)

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: 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



(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- This is concept clause, but the requirement spelt out in a) to d) shall be complied to
- For control, the extend is based on risks

(Compliance best practice)

8.4.2 Type of extend of control

1. *The requirement spelt out in a) to d) of the clause description, shall be complied*
2. *To comply with this clause, external providers shall be evaluated. You can evaluate them on a real-time basis, i.e. with every delivery. You can also evaluate them on a fixed timing say, quarterly, 6-monthly, annually. You need to do a summary for management review. See **Exhibit 24-3**.*

6) 8.4.2.1 Type of extend of control-supplemental (IATF16949)

(Clause Description-Paraphrase)

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.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- A doc process needed to identify outsourced processes and to select types and extend of controls.
- SN Then use to controls. Incorporating requirement can be both yours and customers.

(Compliance best practice)

8.4.2.1 Type of extend of control-supplemental

1. *This clause is specially on control of outsourcing*
2. *Organization should spell out the controls required, in a documented information e.g. Procedure, Compliance Matrix etc. This is however seldom seen. See **Exhibit 24-4** for a specimen.*
3. *Internal and customer requirements shall be included in the controls. Control priority shall be based on risk and supplier performance*
4. *The automotive critical criteria shall also be monitored: premium freight, customer disruption and special status notification. See **Exhibit 22- 7**.*

7) 8.4.2.2 Statutory and regulatory requirements (IATF16949)

This clause has been discussed in Chapter 19. Please refer

8) 8.4.2.3 Supplier QMS development (IATF16949)

(Clause Description-Paraphrase)



The organization shall require their suppliers of automotive products and services to develop, implement, and improve a quality management system certified to ISO 9001, unless otherwise authorized by the customer [e.g., item a) below], 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:

- a) compliance to ISO 9001 through second-party audits;
- b) certification to ISO 9001 through third-party audits; unless otherwise specified by the customer,
- c) 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;
- d) certification to ISO 9001 with compliance to IATF 16949 through second-party audits;
- e) certification to IATF 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body).

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.4.1.2 of the same title, in the previous version of ISO/TS16949. .
- Previous requirements are retained, with more methods provided. See clause details above. However, Option a) has been removed by SI-8. Suppliers therefore shall have min ISO9001 certification by accredited CB, unless waiver given by customer.
- There are also some other minor modifications of the clause by SI-8. Refer below for details.

(Compliance best practice)

8.4.2.3 Supplier QMS development

1. *To demonstrate all relevant suppliers are certified to ISO/IATF, you need copies of their current certificates.*
2. *Check if the certificates are genuine otherwise it is a finding. In recent years, there are certificates issued from unaccredited CB. And of late, there are also fake AB (Accreditation Body). Accredited AB are generally the national standards organizations of each member state (country), and within the IAF. You need to check the CB, and AB to see if they are traceable back to IAF. See **Exhibit 24-5**.*
3. *You also need to check if suppliers have actually been audited every year. Ask for the audit report to make sure it is still valid. See **SN23-10** for explanation.*

9) 8.4.2.3.1 Automotive product-related software or automotive products with embedded software (IATF16949)

(Clause Description-Paraphrase)

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.

(Highlights of the clause)



- (Ref to old Standards). This clause is totally new
- Refer chapter 19 for background info. 8.4.2.3 This is a job done by design team, The clause same, expect responsibility by suppliers
- to check supplier's software development process. Don by done by supplier
- Self- assessment using responsibility to be supplier

(Compliance best practice)

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

This has been discussed in Clause 8.3.2.3, Chapter 22. Please refer.

10) 8.4.2.4 Supplier monitoring (IATF16949)

(Clause Description-Paraphrase)

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.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause 7.4.3.2, of the same title, in the previous version of ISO/TS16949.
- The 3 critical controls for customer satisfaction from the previous lists are listed as: b) customer disruption, d) premium freight, e) special status remained to be controlled
- a) and b) are common KPI for purchasing. Item f) probably refers to OEM only.
- Note that for b), yard holds and stop ships are considered as customer interruptions
- Essentially only b) d) and e) needs to be ensure reporting

(Compliance best practice)

8.4.2.4 Supplier monitoring

1. You need to ensure the 3 critical automotive criteria are fulfilled: b) d) and e) of clause description. Note that the tracking shall be 'event-count' and not 'value'.
2. This tracking is important, as the results will be used for supplier performance evaluations. See **Exhibit 24-6**.
3. There is also a similar set of controls by the sales department, but that is monitoring on your own performance to satisfy the customers. However, you can derive your supplier control data from there.

11) 8.4.2.4.1 Second-party audits (IATF16949)

(Clause Description-Paraphrase)

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 assessment;
- b) supplier monitoring;
- c) supplier QMS development;
- d) product audits;
- e) process 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 may be found in the IATF Auditor Guide and ISO 19011.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- The audit can be used to check on several purposes, see a) to e)
- Criteria for need, type, frequency, and scope of second-party audits.
- Retain audit records and follow up action
- If for general QMS audit, then automotive process audit shall be used
- Meaning if the audit is not for the entire QMS, the audit method can differ.

(Compliance best practice)

8.4.2.4.1 Second-party audits

1. Clause 8.4.2.4.1 is written quite fragmentedly, a Supplier Audit Model is proposed to link up the various requirements for systematic management. Clause 8.4.2.5 can also be included. See **Exhibit 24-7** for details.
2. Other useful specimens for this clause:
 - a) Second-party Audit Schedule **Exhibit 24-8**.
 - b) Second Party audit report **Exhibit 24-9**
 - c) Specific objectives audit report checklist **Exhibit 24-10**
 - d) General QMS audit report checklist/Self-audit checklist **Exhibit 24-11**

12) 8.4.2.5 Supplier Development (IATF16949)

(Clause Description-Paraphrase)

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.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- Active suppliers based on needs from a) to d)

(Compliance best practice)

8.4.2.5 Supplier Development

1. *This area of development is on improvement of weaknesses found*
2. *There are many sources and areas to cover. To be realistic, you need to be pragmatic, as you do not have much time for this.*
3. *Just select areas of weaknesses that relate to your problem now, e.g. request a supplier to improve their problem-solving knowledge. You may tell them to attend an external training. And you visit to follow-up and verify improvement.*

13) 8.4.3 Information for external providers (ISO9001)

(Clause Description-Paraphrase)

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.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.4.2 Purchasing Information, in the previous version of ISO9001.
- Last time a) c). QMS requirement not mentioned, but expected
- This is meant to inform suppliers of the requirements a) to f)

(Compliance best practice)

8.4.3 Information for external providers

1. *P/O normally has product description, quantity, price and expected date of delivery.*
2. *Other information given a) to f) of Clause Description, are generally contained in contracts, and therefore there is no need to repeat them on the P/O.*

14) 8.4.3.1 Information for external providers-supplemental (IATF16949)



(Clause Description-Paraphrase)

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.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- Pass down all applicable statutory and regulatory requirements, special product and process characteristics, all the way to the point of manufacture.

(Compliance best practice)

8.4.3.1 Information for external providers-supplemental

1. Ensure all applicable statutory and regulatory requirements, special product and process characteristics, are passed down the line, all the way to the supply chain
2. The best time to inform suppliers is when awarding the contract.

15) 7.2.4. Second Party Auditor Competency (IATF16949)

(Clause Description-Paraphrase)

The organization shall demonstrate the competence of the auditors undertaking the second-party audits. Second-party auditors shall meet customer specific requirements for auditor qualification and demonstrate the minimum following core competencies, including understanding of: (a) the automotive process approach to auditing, including risk based thinking; (b) applicable customer and organization specific requirements; (c) applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit; (d) applicable manufacturing process(es) to be audited, including PFMEA and control plan; (e) applicable core tool requirements related to the scope of the audit; (f) how to plan, conduct, prepare audit reports, and close out audit findings.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- Second-party auditors shall be competent a) to f)

(Compliance best practice)

7.2.4. Second Party Auditor Competency

1. The requirement of a) to f) of Clause Description, shall be listed in a document showing qualification of a second party auditor. See **Exhibit 33-4**
2. For convenience in management, this information is generally listed together with the internal auditors lists.



16) SIs & FAQs

SI Nbr	IATF Clause	Description
8 <i>Revised</i>	8.4.2.3 Supplier quality management system development	<p>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 organizations becoming certified to this Automotive QMS Standard.</p> <p>Using a risk-based model, the organization shall define a minimum acceptable level of QMS development and a target QMS development level for each supplier.</p> <p>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 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: 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:</p> <ul style="list-style-type: none"> a) compliance to ISO 9001 through second-party audits; b) certification to ISO 9001 through third-party audits; unless otherwise specified by the customer, suppliers to the 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; c) 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; d) certification to ISO 9001 with compliance to IATF 16949 through second-party audits;
8 <i>(cont.) revised</i>	8.4.2.3 Supplier quality management system development	<ul style="list-style-type: none"> e) certification to IATF 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body). <p>NOTE: The minimum acceptable level of QMS development may be compliance to ISO 9001 through second-party audits, if authorized by the customer.</p> <p>Rationale for change:</p> <p><i>Clarified the expected supplier quality management system development progression. This approach supports the "Risk Based Thinking" concept emphasized throughout Section 8.4 of the standard. Additional clarification added with "as applicable" in the first paragraph to address those organizations that are not eligible for IATF 16949 certification (examples including but not limited to the following: scrap metal suppliers, trucking companies who provide transport and logistics support, etc.).</i></p>
7	8.4.2.1 Type and extent of control - supplemental	<p>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.</p> <p>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.</p> <p>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.</p> <p>Rationale for change:</p> <p><i>Clarify the organization's responsibilities for pass through characteristics.</i></p>

15	3.1 Terms and definitions for the automotive industry	<p>embedded software</p> <p>Embedded software is a specialized programme stored in an automotive component (typically computer chip or other non-volatile memory storage) specified by the customer, or as part of the system design, to control its function(s). To be relevant in the scope of IATF 16949 certification, the part that is controlled by embedded software must be developed for an automotive application (i.e., passenger cars, light commercial vehicles, heavy trucks, buses, and motorcycles; see Rules for achieving and maintaining IATF Recognition, 5th Edition, Section 1.0 Eligibility for Certification to IATF 16949, for what is eligible for “Automotive”).</p> <p>NOTE: Software to control any aspect of the manufacturing process (e.g., machine to manufacture a component or material) is not included in the definition of embedded software.</p> <p>Rationale for change: <i>Minimize confusion regarding embedded software and what is applicable. Deleted IATF 16949 FAQ 10.</i></p>
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FAQ	IATF Clause	Questions and Answers
15	8.3.2.3 Development of products with embedded software	<p>QUESTION: What is the acceptable method to assess a supplier’s software development capability?</p> <p>ANSWER: The intent of IATF 16949, Section 8.3.2.3 is to apply the same level of rigor to the development of software as is expected in the development of hardware parts. Just like parts, software has defined performance, operating conditions, known inputs, specified outputs, parameters of environment (e.g. size of the file), regulatory requirements (if any), known failure modes, usage profiles, variability of conditions of operation, etc. The planning, designing, writing, testing, confirming and production validation phases in the development of software are not very different in concept from the development of hardware parts. IATF 16949 provides a robust framework to validate that all necessary steps have been taken to design, verify, and produce hardware parts that continue to meet specification in mass production. While similar in concept, those steps are not the same for the development of software. Therefore, a different set of criteria are used to evaluate the methods used to develop software.</p> <p>Those criteria are not included in IATF 16949; therefore, other methods are referred to, such as Automotive SPICE and CMMI. There may be other acceptable methods available identified by some customers. Each customer may have a preferred tool to assess supplier software development capability. The organization should ask their customer(s) to confirm the acceptable assessment tool. Each customer may also specify a different approach used (e.g., customer on-site assessment, supplier self-assessment, or a combination of both).</p> <p>The role of the IATF 16949 internal or external auditor is not to have the knowledge to conduct the Automotive SPICE or CMMI assessments. However, the internal or external auditor should be familiar enough with the assessments to be able to recognize when a software assessment requirement has not been met and that there are corrective action plans in place, with the</p>
15 (cont.)	8.3.2.3 Development of products with embedded software	<p>appropriate resources assigned. The IATF 16949 internal and external auditor should also know if the customer participates in that software development assessment and how that is documented.</p>
16	8.4.2.4.1 Second-party audits	<p>QUESTION: If there is low risk with an organization’s supplier(s), are 2nd party audits required? What is the intent?</p> <p>ANSWER: The risk-based thinking approach, driven by ISO 9001:2015, needs to be incorporated for supplier management. The risk analysis needs to be completed and depending on the results of the risk assessment (see below), then a 2nd party audit may not be required.</p> <p>To support the risk analysis, the organization needs to consider criteria such as: supplier certification status, commodity complexity, new product launch(es), significant employee turn-over, product quality issues, delivery issues, customer specific requirements, and other risks to the organization or to their customer(s).</p>

17) Supplementary Notes

Legend: HOC= Highlights of Clause, CBP= Compliance Best Practice, S&Q= SIs & FAQ, EXH= Exhibits

Clause	Section	Clarification Subjects
8.4.1, 8.4.1.1	CBP	SN24.1. What are some of the important pitfalls in external provider selection process?
8.4.1.2	CBP	SN24.2. What is the purpose for auditing potential suppliers onsite?
8.4.1.2	CBP	SN24.3. How do we evaluate non-direct suppliers e.g. transporter, or calibration labs?
8.4.1.3	CBP	SN24.4. If nominated supplier are not performing e.g. on quality and on-time delivery, what can we do?
8.4.1.3	CBP	SN24.5. For nominated suppliers, do I still have to fill up an application form, since we do not have to approve?
8.4.2.1	CBP	SN24.6. Why outsourced suppliers need to be given extra control?
8.4.2.4	CBP	SN24.7. Some outsourced processes cannot be checked by incoming QC, as we do not have the facilities or equipment. What can we do?
8.4.2.3	CBP	SN24.8. Why do we insist on service providers such as transporters, machinery repair workshop, tooling suppliers, to have ISO9001? Does it mean all suppliers?
8.4.2.3	CBP	SN24.9. How to check on bona fide and fake CB & AB?
8.4.2.3	CBP	SN24.10. Is the valid ISO9001 certificate a fool-proof way to check the validity of certification?
8.4.2.4	CBP	SN24.11. What is the meaning of special status?
8.4.2.4	CBP	SN24.12. Why IATF only wants event count (frequency) for 3 critical, and not the value?
8.4.2.4.1	CBP	SN24.13. Are nearby suppliers given same privilege for self-audit, instead of onsite audit?.
8.4.2.4.1	CBP	SN24.14. What are the pitfall of self-audit system? What can we do to make it work?
8.4.2.4.1	CBP	SN24.15. What if despite of several improvement attempts, the suppliers still fail to get the minimum passing mark?
8.4.2.4.1	CBP	SN24.16. What if despite warning, dishonesty still prominent in the self-audit process by a particular supplier?
8.4.2.4.1	CBP	SN24.17. Must all supplier auditors be qualified at core tools?
8.4.2.4.1	CBP	SN24.18. How do we decide on which suppliers to conduct second party audit?

SN24.1. What are some of the critical pitfalls in external provider selection process?

3 common ones are:

- a) selection process is not intended to be effective. Verifications are not checked properly or, assumed.
It is like filling up the form for formality
- b) no onsite audit for critical materials or components, especially those made to specifications
- c) technical products are purchased based on price, and there is no technical pre-qualification before purchase

SN24.2 What is the purpose for auditing potential suppliers onsite?



Not all suppliers need to be audited before selection. Those acting as distributors for manufacturers e.g. (a Dupont distributors) you probably don't need to visit because the material is customer-directed. The distributors are only keep inventory and doing delivery. There is nothing much to see except on inventory system and logistics.

But for a supplier producing parts based on your specs , there is a lot of things that can go wrong, from quality to ontime delivery, which can be traced back their operations and facilities. An onsite audit will allow you to detect weaknesses to base your decision on selection. Should you decide to appoint even under imperfect conditions, you still have a chance to help them improve by pointing out the weaknesses.

SN24.3 How do we evaluate the performance of non-direct suppliers e.g. transporter, or calibration labs?

Usually direct and indirect materials are evaluated on real-time basis. When a shipment arrives, judgement is made, and this is summarized every month. For services, you can do an annual instead of monthly to save time. See **Exhibit 24-3**. Note that the 3 critical customer satisfaction criteria, are also to be evaluated as they are equally applicable.

SN24.4. If nominated supplier are not performing e.g. on quality and on-time delivery, what can we do?

You can feedback to customers and let them deal with the situation. If you have someone proven on your supplier list, you may also propose to the customer, as a possible replacement.

SN24.5. For nominated suppliers, do I still have to fill up an application form, since we do not have to approve?

Yes, you should still do. The form has a lot of information you may need to manage the supplier. Remember the responsibility of managing the supplier is still yours?

SN24.6. Why outsourced suppliers need to be given extra control?

Outsourced supplier are away from your site, control is harder. What is more relevant is some of these suppliers are specialists in their own right, and you know very little about their technology and knowhow. Examples are painting and plating. To be in some control, you need to define early what can be checked at your end. Otherwise you are assuming a very high risk.

SN24.7. Some outsourced processes cannot be checked by incoming QC, as we do not have the facilities or equipment. What can we do?

Yes you can check. What you mean is you do not have facilities to measure or test. That's not a mandatory requirement of IQC. IQC can be based on submitted data from the suppliers, or third party lab, depending on your agreement with them. These are often known as certificate of conformance, Outgoing report, mil cert, cert of analysis etc. You can still generate a report based on such information.

SN24.8. Why do we insist on service providers such as transporters, machinery repair workshop, tooling suppliers, to have ISO9001? Does it mean all suppliers?

There is no exemption given to service providers. They have to be ensured of conforming to requirements, your requirements. See 8.4.1.

There is a lot of latitude given. Your priority should be those that can affect quality (e.g. calibration lab), delivery (e.g. transporter), reliability (e.g. maintenance & repair services). The rest can be left alone.



SN24.9. How to check on bona fide and fake CB & AB?

Real ABs are part of the IAF. In fact most of them are national standards institutes of member countries. In other words, they are the owners of ISO in Geneva. Some examples are UKAS (UK), ANAB (USA), DKKKS (Germany). Cofrac (France), DSM (Malaysia), BSP (Singapore). The fake ones are just private companies. You can check on the website of ISO if a particular AB is bona fide.

Fake CB can either be without accreditation from a bona fide AB, with dishonest intent. It is good money when you do not have to share with any upline. Many a time, customers do not know the difference. Another possibility is the CB got an accreditation from a fake AB. Check on the AB, and check on the AB on MLA website. See **Exhibit 24-5**.

SN24.10. Is the valid ISO9001 certificate a fool-proof way to check the validity of certification ?

Not so. Certificates are given out for 3 year, subject to surveillance audits. If your supplier stops after the first year, the old cert can still be used to give a false impression that the certificate is still valid. This comes about because the CB did not retrieve the certificates once issued, all the more with e-certs, which is impossible to delete once mailed out. If in doubt you can check the CB website for status of the certification, or request a copy of the audit report by CB. The second method has some side benefits, you can also see what the report says about your supplier and any weaknesses (NC, OFI), that can give you some advance warning of trouble.

SN24.11. What is the meaning of special status?

The full term is 'special status notification' from customers. This is a negative thing, saying you are have big issue with quality or delivery. You are generally not allowed to bid for new business anymore. Your shipment will also be under strict surveillance through QC arrangements & special marking etc. If you still take it easy, this will be the beginning of the end.

SN24.12. Why IATF only wants event count for 3 critical customer satisfaction criteria, and not the value?

For IATF, the event-count will tell frequency of occurrence that further investigation can be done. Further investigation will surface root cause of problems e.g. production, QAQC, purchasing or others. The value may have some significance to your organization, but not IATF. You can compile both data in your total controls. See **Exhibit 24-6**.

SN24.13. Can nearby suppliers be given same privilege for self-audit, instead of onsite audit?.

The suggested self-audit method is to save some cost for the organization. But extending the same for everyone, including the local suppliers is defeating the purpose. Second-party audit is to audit suppliers at onsite to check on compliances and non-compliances. Using the self-audit to avoid the second party is going against the intent of IATF. It is not acceptable.

SN24.14. What are the pitfalls of self-audit system? What can we do to make it work?

The most common pitfall is suppliers giving good score to the questions asked. With a high score, a second party audit is avoided. There are also some who will score full marks to all questions. This is an indication of the person responsible is either flaunting the system or do not understand. Warning should be given. Most suppliers would do it to a certain degree. You have the history with them to judge if the scores are reasonable. If not, you call out on them and request a re-score.

SN24.15. What if despite of several improvement attempts, the suppliers still fail to get the minimum passing mark?



An onsite audit will be in order. You can get them to pay for the cost, or part of it, to encourage improvement.

SN24.16. What if despite warning, dishonesty still is prominent in the self-audit process by a particular supplier?

You should consider to suspend or terminate the supplier.

SN24.17. Must all supplier auditors be qualified at core tools?

No, not all. Some second party auditors are only required to check on non-technical processes. For example, if you are auditing purchasing and stores, you do not need core tool competency. If you audit production processes, or QC, PPAP, then core tools are needed. Just make sure the non-core tool competent auditors do not audit core-tool activities.

SN24.18. How do we decide on which suppliers to conduct second party audit?

You should first classify your suppliers to signify the degree of criticality. Critical supplier should be audited irrespective of performance. Frequency of say once in 1-3 years should be reasonable.

The rest of the suppliers will be audited based on their performance and also evaluation results. The model suggested in this manual allows self-audit to cut down your involvement. When self-audit still not meeting the cut, the suppliers will be audited. There are also some other reasons for auditing the supplier. See **Exhibit 24-7**.



Exhibit 24-1. Approved Supplier List

Approved Supplier List

S/N	Supplier Name / Address	Approved scope	Classification	Current Qualification	Appointed Since
1	Platmax	Electroplating services	B	ISO9001	2012

Classification: A: Safety-Related, B: Regulatory-Related, C: Quality-Critical, D: Normal Purchases

Remarks given in this section explain on the Exhibit. Do not include them as part of the document

- This ASL has an extra column, classification. In this example, suppliers are classified into 4 classes. You can decide on your own categories
- The main purpose is to draw extra attention on the critical ones. The classification also helps to decide which suppliers need to be audited (second party) due to critical nature.

Exhibit 24-2 Supplier Selection Information

Vendor Information		
Company Name		
Address		
Telephone	Fax	E-mail
Year incorporated	Years in business	Paid-up Capital
Contact Person, Designation and Hand-phone No.		
Specializes in the supply of		Recommended by whom?
Plant built-up area	Branches built-up area	
Manpower		
Management System certified?		
<input type="checkbox"/> No <input type="checkbox"/> Yes, ISO 9001:2015, Others (Specify)		
2 Major customers serving currently	Annual Sales Turnover for last 3 years	
2 Major Production Machineries and numbers	Major Quality/testing Equipment and numbers	
Capacity available and delivery lead time		
*Price and Payment Term (please provide separately)		
Declaration: I/we the undersigned confirmed that the information furnished above is true.		
Name:	Signature, date & Company Stamp:	
Designation:		
For office use:		
1. Any checking of sample? If yes, result? 2. Any site visit/audit? If yes, result? 3. Overall result: poor/ satisfactory/ good (circle)		
Evaluated by	Recommendation: <input type="checkbox"/> OK; Given Provisional Status <input type="checkbox"/> Not Good Enough, decline	
Name, signature & date	Approved by: Date"	

Remarks given here explain on the Exhibit. Do not include them as part of the document

- This is actually an application form. Each section shall be filled and evaluated
- The evaluation shall be based on all the information and data. Request suppliers to provide attachment as necessary. Verify data and conduct onsite audit, if necessary
- Recommendation is made by the lead assessor, and approved by relevant authority



Exhibit 24-3 Supplier Evaluation including 3 critical

Type of Supplies Metal		Year 2019	Venue Conference Room	Date 2-4-2020	
Evaluators XXX (purchasing), XXX (warehouse), XXX (Production-user)					
No	Evaluation Areas	Supplier A	Supplier B	Supplier C	Supplier D
1 (totally unacceptable), 2 (Poor), 3 (Borderline), 4 (Good), 5 (Outstanding)					
S1	A. Standard criteria				
	Quality	5	4	5	2
S2	On-time Delivery	5	5	5	5
S3	Service & Helpfulness	4	4	5	5
S4	Pricing	3	4	3	4
S5	Response Speed	4	5	4	5
	Total	21/25	22/25	22/25	21/25
	%	84%	88%	88%	84%
	B. Automotive Criteria	<i>Deaurnomy Case</i>			
A1	Caused line down	Cases	-%	Cases	-%
		10%			
A2	Caused premium freight	2	10%	1	5%
A3	Caused special status notice				
	Net %	74%		83%	88%
	Recommend to use	Yes/No	Yes/No	Yes/No	Yes/No
	Management Approval				
Ratings/Decision Guide: 71% or above (use), 51-70 %, (Need improvement) 0-50%, (not to use /terminate).					

3 critical automotive controls

Remarks given in this section explain on the Exhibit. Do not include them as part of the document

- This is an annual evaluation summary on suppliers. In this example, similar suppliers are group in clusters, for evaluation and comparison.
- For materials, supplier performance is generally evaluated on every 'shipment' basis. There may be some calculations to be done to get to this step.
- For service suppliers (transporters, calibration labs, critical maintenance contractors), they can be evaluated directly, once a year, using this form
- What is interesting is section B that evaluates on the '3 critical automotive controls'. These are very important criteria and demerits points are given for occurrences. For special status, the supplier status is suspended immediately until resolved

Exhibit 24.4. Describing control on outsourcing

ISO9001:2015(Black Fonts) IATF16949:2016 (Blue Fonts)
QMS Compliance Matrix

ISO16949:2016 Requirement	Compliance Details	Relevant Document Location
8.4.1.3 Customer-directed sources (also known as "direct-buy"	Customer-directed sources for supplies shall be adopted, with documentary evidence. However, the organization continues to apply the control on these external providers, as in 8.4.1.3, unless exempted by the customers.	QP6-1 Purchasing
8.4.2 Type of extend of control	Maintain control of both the external providers and well as their supplied item or work. QP6-1 provides the control in selection, regular monitoring of performance. External providers are subject to periodic re-evaluation. Linkage of external providers' performance to resulting output is established. For externally provided products and services, incoming quality inspections or evaluations are performed.	QP6-1 Purchasing
8.4.2.1 Type of extend of control-supplemental	Each outsourced processes is control tightly. The type and extend of controls is determined, to ensure meeting requirements (both internal and customer requirements). Relevant outsourced suppliers are briefed and compliance method agreed on. Depending on actual performances and associated risks, controls is tightened or reduced. This is explained on each outsourcing plan.	QP6-1 Purchasing
8.4.2.2 Statutory and regulatory requirements	Documented process to ensure externally provided processes, products and services conform to statutory and regulatory requirements of: a) Shipment country, b) receiving country, c) final destination country. The last one is required only if provided.	QP6-1 Purchasing
8.4.2.3 Supplier QMS development	In accordance with the requirement of IATF16949, external providers shall be minimum to ISO9001, unless documented waiver is given by customers. QPXXX Purchasing	

Control of outsourcing can be described in the compliance matrix to replace the need for a documented procedure

- Remarks given in this section explain on the Exhibit. Do not include them as part of the document**
- This is taken out of a Compliance Matrix. The control method on outsourcing is explained here briefing , under the clause 8.4.2.1, and further refer to outsourcing plans.
 - This is only one method of illustrating on the approach. The message can also be written on procedures, or the QM, if a full manual is used.

Exhibit 24-5. IAF & AB on authenticity of certificates

Exhibit 24-5 Authenticity of ISO Certificates

Certificate CN14/01295.00, continued

NeoPhotonics (China) Co., Ltd.
ISO 9001:2015

Issue 2,
 Detailed scope:
Design and manufacture of optical devices, including passive optical devices and optical modules

Further Certifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organisation




Additional facilities

NeoPhotonics (Dongguan) Co., Ltd.
 Section B of B9, Conrad Hi-Tech Park, South Section of Chang Nan Road, Shaogsha Village, Zhen'an, Chang'an Town, Dongguan City, Guangdong Province, P.R. China

Manufacture of optical devices, including passive optical devices and optical modules

NeoPhotonics (China) Co., Ltd. Wuhan R&D Center
 Bldg D1, 1.2 Phase, Optics Valley Software Park, No.1, Guanshan Avenue, East Lake Hi-Tech Development Zone, Wuhan City, Hubei Province, P.R. China

Design of optical devices, including passive optical devices and optical modules

This is Certification Body. Licenced from Accreditation body

This is managing ISO Certification

This is the Accredited Body, which is appointed by IAF- Check this

Showing results for **accreditation body members**
 Search instead for **accreditation body members**

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Accreditation Body Members: by Name

IAF Members & Signatories. A2LA : American Association for Laboratory Accreditation.
 ACCREDIA: Italian Accreditation Body. ANAB : ANSI National Accreditation Board. BoA : Bureau of Accreditation (Vietnam) BELAC : Belgian Accreditation Body. CAI : Czech Accreditation Institute (AIČeský institut pro akreditaci, o.p.s.)

Search this site for Accreditation body to see authenticity

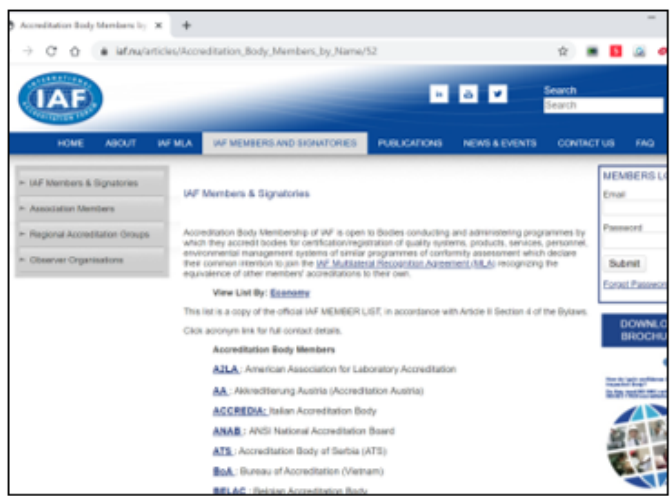




Exhibit 24-6. Supplier Tracking on 3 critical criteria

Exhibit 24-2. Supplier Tracking on 3 automotive critical criteria

Month		Compiled by					Approved by
No/Supplier No	Supplier Name	Caused line down	Caused premium freight (inbound)	Caused premium freight (outbound)	Caused special status notice	Remarks/ deviation Details	
1	SALX	0	1	0	0	Material ran short. Cost absorbed by supplier. OFI	
2	Premier Metal	0	2	0	0	Problem due to customer ramp up demand, customer pays for extra freight. OK	
3	HDtQ Transport	1	0	0	0	Transport truck broke down. Transported rush another consignment from factory here. Miss timing by 1 hour. NG demerit point and compensation	

Remarks given in this section explain on the Exhibit. Do not include them as part of the document

- This is a recording form for tracking the performances of suppliers on the 3 automotive critical criteria
- The results will be used for year-end evaluation. See Exhibit 24-3.

Exhibit 24-7. Second Party Audit Management Model

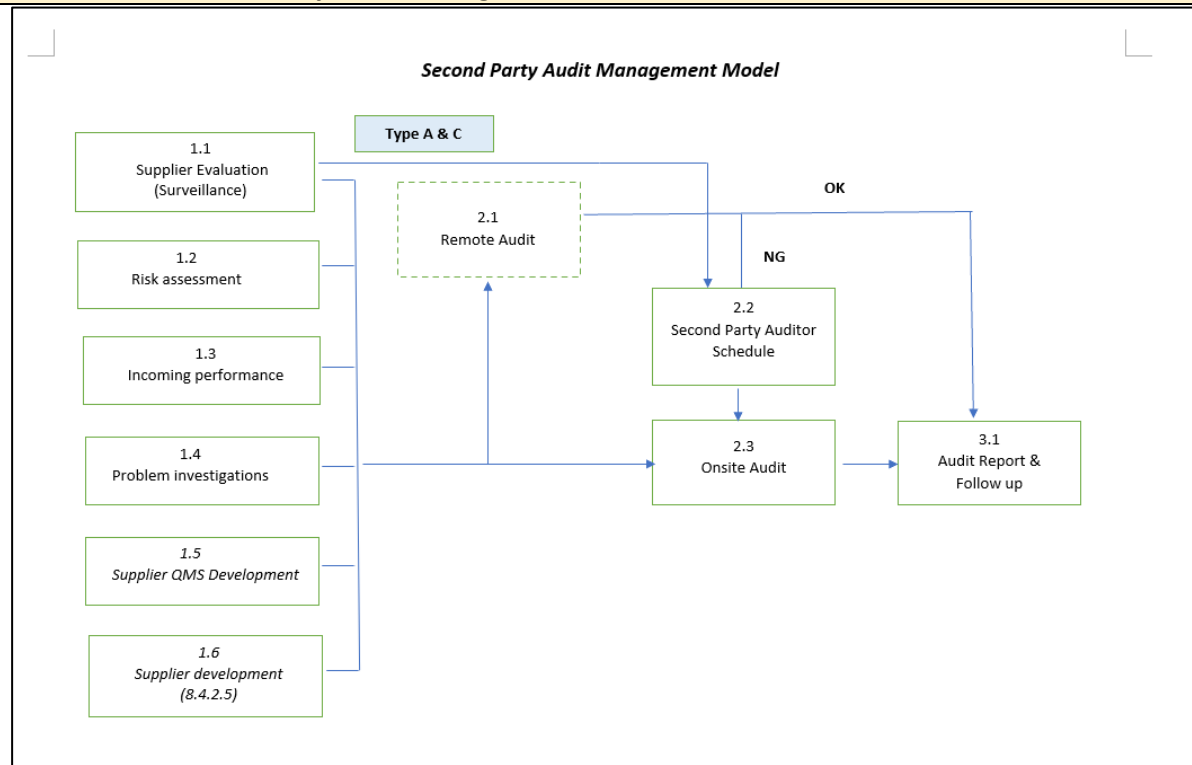


Exhibit 24-7. Page 2

(Second Party Audit Guidelines)

Step	Description	Application	Frequency of 2P Audit	Audit Objectives & Report
1.1	Supplier Evaluation	<ul style="list-style-type: none"> Failing supplier evaluation, conducted by the organization 	Type A & C: once every once in 3 years Type B&D Failing min marks (70%)	General
1.2	Risk assessment	<ul style="list-style-type: none"> Risks on quality and safety pertaining to Risk and Opportunity studies Specific area to assess e.g. statutory and regulatory, safety, inventory system, preservation system etc 	As required	Specific
1.3	Poor performance	<ul style="list-style-type: none"> Incoming quality or delivery, certification issues by CB audits. Frequent or significant incoming quality or delivery problems 	As required	Specific
1.4	Problem investigations	<ul style="list-style-type: none"> Linkage from organization's production or quality problem, or from final customer. Investigation of a specific problem from organization's internal problems, or final customers' problems. 	As required	Specific
1.5	Supplier QMS Development	<ul style="list-style-type: none"> Where a further progress in QMS system is required by the organization, or final customer, e.g. from ISO9001 to IATF 16949. An supplier is requested to upgrade its QMS from ISO9001 to IATF 16949. Example a metal stamping supplier 	As agreed	Specific
1.6	Supplier development (8.4.2.5)	<ul style="list-style-type: none"> Development of supplier's knowledge or capabilities. 	As agreed	Specific

Exhibit 24-7. Page 3

Step	Description	Application	Frequency	Remarks
2.1	Remote Audit	<ul style="list-style-type: none"> Suppliers situated far away e.g. foreign countries or >100 km away, may be granted remote-audit instead of onsite audit Further exemption can be given to suppliers having no performance problem and passing self-audit with >90%. 	Type A&C: once every once in 3 years Foreign suppliers- self audit Type B&D Failing min marks (70%)	NA
2.2	Second Party Auditor Schedule	<ul style="list-style-type: none"> A schedule to coordinate dates for second party audits 	The schedule is prepare at beginning of year, but modified as time progresses	NA
2.3	Onsite Audit	<ul style="list-style-type: none"> As Standard requirement of 8.4.2.4.1. When remote audit not granted When failing remote audit <80% 	As applicable	NA
3.1	Audit Report & Follow up	<ul style="list-style-type: none"> Audit Report shall summarize findings pertaining to the audit objectives. Except from 1.1, which is general and uses full QMS audit report, other audits are specific and can use specific objective reports 	After each audit	NA

Remarks given in this section explain on the Exhibit. Do not include them as part of the document

- Second-party audit is one of the hardest clauses to comply. Various degree of compliances is seen, but somehow something is missing, or not quite right.
- We link up the various requirements and sub-requirements into a flow chart to guide compliance
- When applied this way, the second party audit can be a very useful tool to develop your suppliers too

Exhibit 24-8. Second Party Audit Schedule

Second Party Audit Schedule																
Category: A. Supplier surveillance, B. Risk Assessment, C. Incoming Performance, D. Problem Investigation, E. QMS Development, F. Supplier development																
No	Supplier	Type	Objectives	P/A	Jan 18	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Supplier AA	A	Full QMS audit	Plan		x										
				Actual												
2	Supplier BB	B	Inventory system to ensure no interruption of supply	Plan			x									
				Actual												
3	Supplier CC	A	Full QMS	Plan				x								
				Actual												
4	Supplier DD	C	Check on Frequent issue of plating thickness	Plan					x							
				Actual												
5	Supplier EE	E	QMS upgrade to IATF16949, Check on progress	Plan											x	
				Actual												
6	Supplier FF	F	NCP and CAPA competency to increase	Plan			x					x				
				Actual												
7	Supplier GG	D	Welding complaint from customer. Supplier is GG for the complaint	Plan												
				Actual												
8				Plan												
				Actual												
9				Plan												
				Actual												
10				Plan												
				Actual												

Note that there is no planned date for urgent cases

Exhibit 24-9. Second Party Audit Report

Supplier Audit Report	
Supplier: Star Polymers	Date 10 Jul 2019
Type: <input type="checkbox"/> Supplier surveillance <input checked="" type="checkbox"/> Risk Assessment <input type="checkbox"/> Incoming Performance <input type="checkbox"/> Problem Investigation <input type="checkbox"/> QMS Development <input type="checkbox"/> Supplier development	
Objectives of Audit 1. To study their inventory system in supporting our new product XYZ	
Audit Team: Leader: Roland (QMR), Siva (purchasing), Fauzi (Warehouse)	
Audit Plan: 1. understand their current inventory method 2. understand how they provide stock to cater for all their customers 3. understand how the forecast provided to them is taken into the system 4. take the real case of the next 6 months against their stock levels for judgement	
Conclusions 1. They are using Min stock as basis of stock-keeping, min 2 months in warehouse, 1 month in transit. 2. The data is based on forecast from customers. If no forecast, historical ordering pattern x 0.8 will be used. Sometimes call up customer to verify 3. Our forecast is taken as Point 2 above. 4. Take the real case of next 6 months. EXW2000 needs average 2000 kg/month. From the orders place with manufacturers, the quantity is 6000-8000 kg. OK. There is another customer, requiring 4000kg per month. Therefore the inventory system is satisfactory.	
Follow-up Actions 1. Supplier request if we can provide rolling forecast so that they can estimate better	
Remarks given in this section explain on the Exhibit. Do not include them as part of the document <ul style="list-style-type: none"> What normally seen in the field, is the supplier audit team will submit a QMS checklist with notes, as the report. This is OK for normal surveillance audit, but not suitable for specific-objective audits. This is a specimen for second-party audit that can be used for all types of audits Attachments are: a) for full QMS audit report, attach a full QMS audit checklist , b) for specific-objective audits, attach an open checklist with supporting evidences. 	



Exhibit 24-10. Specific Objective 2P Audit Checklist

Supplier Audit Checklist

(Specific Objective Checklist)

Supplier		Date
Auditors	Auditees	

No.	Check Item	OK?	Finding Notes

Auditor (Sign & Date) _____



Exhibit 24-11. Full QMS 2P Audit Checklist

Second Party Audit Checklist

(Full QMS System Audit)

Supplier _____ Auditor _____

Date _____ Auditees _____

Tick () self-assessment () onsite audit

SN	Audit Area	Audit Notes, Yes/No, Compliance Evidence	Max Marks	Score
1	Management			
1.1	Quality Policy and roles defined.		2	
1.2	Company organization and responsibilities defined		2	
1.3	Involvement of Top Management in Quality Matters		2	
1.4	Internal Quality Audit		2	
1.5	Accreditation to ISO9001; IATF16949, ISO13485; ISO22000 or equivalent where applicable		2	
2	Quality Planning			
2.1	Control Plan or Quality Plan defined		2	
2.2	Customer product requirement		2	
3	Purchasing Process			
3.1	Supplier selection & audit program		2	
3.2	Approved vendor list		2	

Exhibit 24-11. Page 2

12	Manpower			
12.1	Training program		2	
12.2	Competency		2	
13	Improvement			
13.1	Corrective Action - 8D		2	
13.2	CA closure and effectiveness		2	
	Total Score		100.0	
	Grade			
	Recommendations			

Prepared by:

Overall Result (Initial Selection)

90 - 100 : A – Recommended
 75 - 89 : B - Acceptable, need attention
 50- 74 : C - Improvement before appointment
 < 49 : D - Not Recommended

Overall Result (Second Party Audit)

90 - 100 : A – Remain on ASL
 75 - 89 : B - Acceptable, need attention
 50- 74 : C - Improvement before confirmation
 < 49 : D – Suspend/Terminate

Office Use- Management

Remarks given here explain on the Exhibit. Do not include them as part of the document

- This questionnaire/ checklist can be used for both onsite audit and self-audit by supplier
- Note that only 2 out of 9 pages are shown here due to space constraints