

Chapter 19. Product, Service, Statutory & Regulatory Requirements

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0) Introduction

There are several applicable clauses in this chapter. The chapter focuses on customer requirements, which also include statutory and regulatory requirements. Three clauses (8.1.2, 8.5.5, 8.5.5.2) that had received low attention are now added to this chapter for discussion. This area has many FAQ and SI and therefore some emphasis is due.

1) 8.2.2 Determining the requirement of products and services (ISO9001)

(Clause Description-Paraphrase)

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

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

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.2.1 Determining the requirement related to the products, in the old version of ISO9018.
- Previous requirement for post-delivery activities are covered by Clause 8.5.5 of the new standard, and not exempted.
- Apart from that, there is no change to the requirement.
- Full requirement is given in a) to b) of clause description.

(Compliance best practice)

8.2.2 Determining the requirement of products and services

1. *In the ISO9001 context, products may not be made to a particular customer's specifications, but for general market offering. Hence this clause has a special significance, as the organization must decide what will appeal to the customers out there.*
2. *The requirements are identified by many ways, e.g. by assumption, by market survey, by R&D etc.*

3. *The output of this determination becomes the input or starting point for design and development.*
4. *In IATF' cases, customers are known and specs are generally provided or agreed on. Relevant functions are represented in the Core Team to manage the product and manufacturing process design. The requirements are then summarized in the form of Design Objectives or PPAP list. See Chapter 22, design & development, for details.*

2) 8.2.2.1 Determining the requirements for products and services – supplemental (IATF16949)

(Clause Description-Paraphrase)

These requirements shall include recycling, environmental impact, and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes. Compliance to ISO 9001, Section 8.2.2 item (a)1, shall include but not be limited to the following: all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

(Highlights of the clause)

- (Ref to old Standards). There is a new clause, formed from the NOTES of the old 7.2.1.
- Compliance include all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

(Compliance best practice)

8.2.2.1 Determining the requirements for products and services – supplemental

1. *After the design, organization shall ensure other requirements stated above i.e. legal requirements on recycling, environmental impact, and characteristics determined by the organization have been included, where applicable.*
2. *Double-check before handing over the requirement list to Design department, as an error can result in a lot of inconveniences later.*

3) 8.4.2.2 Statutory and regulatory requirements (IATF16949)

(Clause Description-Paraphrase)

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 certain products with statutory and regulatory requirements, the organization shall ensure they are implemented and maintained as defined, including at suppliers' place.

(Highlights of the clause)

- (Ref to old Standards) There used to be a clause, 7.4.1.1 Statutory and regulatory conformity in the older version of ISO/TS16949. The old requirements are retained, with some addition.
- Now the clause included the statutory and regulatory requirement of country of receipt, country of shipment, and country of shipment.
- If customer specify special controls for statutory and regulatory requirements, they shall be complied

(Compliance best practice)

8.4.2.2 Statutory and regulatory requirements

1. On the last paragraph of the clause description, statutory and regulatory controls on products must be complied, and ensured the requirements are cascaded down the supply chain. More information on how to achieve this is given in Chapter 24.
2. The part on statutory and regulatory controls in other countries need some discussions, as it is new. First the definitions of the various types of countries:
 - a. country of receipt: is the country of manufacturing site, where your organization is located
 - b. country of shipment: the country of receiving
 - c. country of destination: where the product are finally sold or used
(Author: definitions of a. and b. above seem to be mixed up)
4. To each of the countries above, you need to understand the statutory and regulatory requirements. concerning the products, application, logistics etc. This kind of information is normally provided by the customers. Your first action should be to request for them
5. For country of destination, it is only required if specified by the customer, and provided by the customer. If they don't, you are exempted. See FAQ-24
6. Irrespective of the sources (either from customer or by organization), the information shall be recorded as evidence. See **Exhibit 19-1**

4) 4.3.2 Customer-specific requirement (IATF16949)

This has been covered in Chapter 6, CSR and will not be repeated here.

5) 8.1.2 Confidentiality (IATF16949)

(Clause Description-Paraphrase)

The organization shall ensure the confidentiality of customer-contracted products and projects under development, including related product information.

(Highlights of the clause)

- (Ref to old Standards).There was a similar clause 7.1.4 Confidentiality in the previous ISO/TS16949 version:
- It is largely a word-for-word reproduction. Hence no change in requirement.
- Full requirement please refer to the clause description

(Compliance best practice)

8.1.2 Confidentiality

1. You are just required to understand the intent and comply. There is generally no need to produce any documentation.
2. IATF Auditors will have an impression how you control confidentiality the moment they enter your premises. It is best not to skip the procedure for registering them as visitors. Issued a gate-pass or visitor tag for wearing, if this is the norm.
3. Another point they may ask is the control of visitation to the production, inspection and design areas. Displaying a sign of entry restriction will be helpful, although not mandatory.
4. Next and more importantly is the control of customer information such as drawing and technical specs. You need to show how this confidential information are being protected against unauthorized leakage. Data access by password for authorized personnel and

levels are expected. Limiting file size so that drawings cannot be sent out, and control usage of USB copying of files are good practice.

5. *You may need to negotiate with customers on the extend you are prepared to abide. Some evidences of approval from customer are required if IATF auditor feels the controls seem to be inadequate.*

6) 8.5.5 Post-delivery activities (ISO9001)

(Requirement-paraphrase)

The organization 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.

(Highlights of the clause)

- (Ref to old Standards). No specific clause in the previous ISO9001. But mentioned in 7.2.1, 7.5.1
- To determine requirements for post-delivery, a list is given as guide, see a) to e) of the clause description. Examples of post-delivery services are given in the NOTE

(Compliance best practice)

8.5.5 Post-delivery activities

1. *There is a tendency for organization to declare there is no requirement on this, because it saves the hassles to prove compliance. But IATF auditors roughly would know what product lines or operations will have post-delivery activities, and you may be asked to justify.*
2. *There is the list given by Clause Description, a) to e) for you to check. It may be a good idea to design a form to record your evidences, based on this list. See **Exhibit 19-2**.*

7) 8.5.5.2 Service Agreement with Customer (IATF16949)

(Clause Description-Paraphrase)

When there is a service agreement with the customer, the organization shall:

- a) verify that the relevant service centres comply with applicable requirements;
- b) verify the effectiveness of any special purpose tools or measurement equipment;
- c) ensure that all service personnel are trained in applicable requirements.

(Highlights of the clause)

- (Ref to old Standards). There used to be a clause 7.5.1.8 of the same title in the old version of ISO/TS16949.
- There is no change in content, but reworded for clarify only

- This area concerns requirements on service centers. This is applicable only if a service agreement exist.
- The full requirements are given in the clause description.

(Compliance best practice)

8.5.5.2 Service Agreement with Customer

1. In most cases, this is not applicable. Applicable situations may be: a) service contract signed between an OEM with a fleet owner, b) certain proprietary supplies that needs onsite support, that an onsite service centre is needed.
2. As the external provider, you need to ensure the service centres are well equipped for the role. Internal and IATF auditors will audit these centres as remote locations.
3. Procedures are recommended to define practices, controls and monitoring. Internal audits can also use the procedure to check for compliances

8) 8.6.5. Statutory and regulatory conformity

This is discussed in detail at Chapter 30. Please refer.

9) SIs & FAQs

SI No	IATF Clause	Description
1	3.1 Terms and definitions for the automotive industry	<p>customer requirements</p> <p>all requirements specified by the customer (e.g., technical, commercial, product and manufacturing process-related requirements, general terms and conditions, customer-specific requirements, etc.)</p> <p>Where the audited organization is a vehicle manufacturer, vehicle manufacturer subsidiary, or joint venture with a vehicle manufacturer, the relevant customer is specified by the vehicle manufacturer, their subsidiaries, or joint ventures.</p> <p>Rationale for change:</p> <p>Customer requirements are developed by vehicle manufacturers for application in their supply chain by the nature of the product realization process. Therefore, where the vehicle manufacturers are being certified, the vehicle manufactures define how customer approvals and/or input are managed.</p>

FAQ IATF	Clause	Questions and Answers
9	8.4.2.2 Statutory and regulatory requirements and 8.6.5 Statutory and regulatory conformity	<p>QUESTION 1:</p> <p>What is the perspective (on statutory and regulatory conformity)? What is considered sufficient evidence of conformity to applicable statutory and regulatory requirements (8.6.5)?</p> <p>ANSWER 1:</p> <p>As defined in 8.3.3.1 g) and 8.3.4.2, the organization is required to have an approach to research, identify, obtain copies of, review, understand, and assure compliance with the statutory and regulatory requirements for the product they are manufacturing in the country where they are manufacturing products and the destination country where they are shipping the products to.</p>

9 (cont.)	8.4.2.2 Statutory and regulatory requirements (cont.) and 8.6.5 Statutory and regulatory conformity (cont.)	<p>The intent of 8.4.2.2 is that the organization designs into their product development methodology/business process(es) and their supplier management methodologies/business process(es), one or more approaches for obtaining confirmation and evidence from their suppliers that the products and services being provided by the supplier comply with the statutory and regulatory requirements of the country where the supplier is manufacturing them, the country where the organization is using them, and the country where the organization ships their product to, if provided by the customer.</p> <p>The intent of 8.6.5 is to require the organization to check the records of conformance/compliance received from the supplier to assure that the lot code, batch number, or comparable traceability information for the product are covered by the evidence provided by the supplier. This could be done upon receipt from the supplier, or while the product is in inventory, but must be done prior to release of the product into the organization's production flow.</p> <p>QUESTION 2: Did the intent of clause 8.4.2.2 change from ISO/TS 16949 to IATF 16949?</p> <p>ANSWER 2: The intent of the clause did not change. The ISO/TS 16949 requirement was "All purchased product shall conform to applicable statutory and regulatory requirements". In this "passive voice" wording, the IATF decided their expectations were not clear. The new requirement is more explicit about what is to be done, when it is to be done, and what evidence is required to support compliance.</p>
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FAQ	IATF Clause	Questions and Answers
24	8.4.2.2 Statutory and regulatory requirements	<p>QUESTION 1: If the organization is not responsible for product design and is therefore only manufacturing products as per the customer's design, is the organization then exempt from the requirements in 8.4.2.2?</p> <p>ANSWER: No, all organizations regardless of their responsibility for product design must satisfy the applicable requirements of 8.4.2.2. The applicable requirements address purchased products, processes, and services for which the organization is responsible.</p>
24 (cont.)	8.4.2.2 Statutory and regulatory requirements (cont.)	<p>QUESTION 4: What level of detail should be provided by the customer regarding the countries of destination? Would a generic statement like "every country globally" be an appropriate response?</p> <p>ANSWER: No, a generic statement such as "every country globally" is not acceptable. The customer is expected to provide to the organization a specific list of countries where the vehicle(s) are initially sold.</p> <p>QUESTION 5: Applicable statutory and regulatory requirements are often linked to the relevant use of a product. Some parts might become a safety-related product, depending on its use. Based on the before mentioned statement, is the customer required to provide the organization with detailed information about the intended use?</p> <p>ANSWER: It is expected that the customer will provide to the organization information of the characteristics that are relevant for the identification of required controls to meet applicable statutory and regulatory requirements (e.g. special characteristics).</p>

24 (cont.)	8.4.2.2 Statutory and regulatory requirements (cont.)	<p>QUESTION 2: Is the organization required to request a complete list of countries of destination from the customer if the list was not provided by the customer?</p> <p>ANSWER: Yes, the organization is required to request a complete list of the countries of destination from the customer if the list was not provided by the customer.</p> <p>NOTE:</p> <ul style="list-style-type: none"> ○ The "country of receipt" is where the organization is located. (Country of the manufacturing site) ○ The "country of shipment" is the customer's receiving location. (Country where the manufacturing site ships to) ○ The "country of destination" is the country where the vehicle is sold. (Country where the final product is initially sold) <p>QUESTION 3: What is the consequence if the customer does not provide the information on the countries of destination to the organization? What is the organization required to document in this situation?</p> <p>ANSWER: If the organization claims that the customer did not provide the necessary information on the countries of destination, the organization should be able to produce written evidence (e.g. letters, emails, meeting minutes, etc.) of their efforts to obtain it.</p>
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10) Supplementary Notes

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

Clause	Section	Clarification Subjects
8.4.2.2	CBP	SN19-1. If we just ship to our HQ or associated companies, do we have to deal with export legal requirements, i.e. for the 3 types of countries?
8.4.2.2	CBP	SN19-2. In the case of supply to a customer in the same country of our location, but finally exported; do we need to deal with statutory and regulatory requirements of the countries they export?
8.4.2.2	CBP	SN19-3. Customer should assist to provide the information. To what level should they assist?
8.1.2	CBP	SN19-4. What kind of evidences to show we are controlling on confidentiality
8.5.5.2	CBP	SN19-5. What kind of evidences we need to show we do not have service agreement with any customers?

SN19-1. If we just ship to our HQ or associated companies, do we have to deal with export legal requirements, i.e. for the 3 types of countries?

Yes. You have to. But you can count on their cooperation. If your contacts in HQ or associated companies are commercial people, there might be some protracted communications to be done. But eventually you will have it resolved.

SN19-2. In the case of supply to a customer in the same country of our location, but finally exported; do we need to deal with statutory and regulatory requirements of the countries they export to?

No, unlikely. They should be doing it as they are likely to be exporting other items to the same associated companies already. However, they may need your input for items they are not familiar with, e.g. in the case of accessories. You should assist in such cases.

SN19-3. Customer should assist to provide the information. To what level should they assist?

The customer should be familiar because they either operate in the those countries or work closely with the resident associates there. But it is your final responsibility to access such information. For country of destination, you should wait for the list from the customer. If there is no list coming forth, request for it. If there is no response, you responsibility stops there, (see FAQ-24) but keep the communications as evidence.

SN19-4. What kind of evidences to show we are controlling on confidentiality?

Such requirements can be found either in the SQM or purchase contracts. Your evidence of compliance is the records of your compliance activities. If it is signages required at the production or at the design office, make sure you have them. If it is email control e.g. max 10 GB limits, show the relevant evidence.

SN19-5. What kind of evidences we need to show that we do not have service agreement with any customers?

You just inform the auditor directly. If he/she wants to verify, he may request to see the purchase contracts. He may even check your measuring equipment master list to spot equipment based outside the main sites.

Exhibit 19-1. Statutory and Regulatory Requirements for Export

Statutory and Regulatory Requirements (Export)

No	Customer	Parts if applicable	Countries (indicate yes/no applicable)		S&R Handled by (Cust/Org)	Applicable laws
			Receipt	Shipment		
1	ABC	1000345CRQ	No	No	NA	NA
2	PQR	TWR-40 series	No	Yes	Organization	Destination. Japan: Special warning label on motor component
3	XYZ	M-335PP Series	Yes	Yes	Organization	Shipment: Japan. Green procurement Destination: EU. RoHS & Reach

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

- This is a quick summary of compliance to applicable statutory and regulatory requirements for exported products.
- If the compliance is handled fully by customer, then you don't have to worry too much. You just build to customer requirement.
- If customers disclose their destination and need you to comply to laws of the exported countries, then you cannot escape responsibility.
- This chart is useful to all relevant departments in the organization e.g. process engineering, purchasing, production and QC.
- If exact statutes or regulations can be stated, it is even better, although not mandatory

Exhibit 19-2. Post-Delivery Activities Determination

Post-Delivery Activities Determination

Business Line: aircon compressors		
Criteria	Actual	Provision
Any statutory requirement in our products, including disposal?	No special requirement, except normal disposal regulations. This will be handled by the last point of service, the OEM service centres, or private service centres.	None
Potential undesired consequences associate with the product	No negative consequences conceivable.	None
Nature, use and intended lifetime of its products and services	No unusual hazards or inconveniences expected	None
Customer requirement for post delivery services	Performance Warranty as requested by Customers. No of years varies.	Compensation to abide by agreement. For management of individual claim cases, follow customer-specified method of handling.
Customer feedback that indicate post-delivery care is needed	Organization very familiar with this business, having been in it for 25 years. Nothing new has been introduced that we are not aware of.	None
Corporate strategy and policy in this area	To work with OEM customer as a team to service their final customer/consumer.	Case to case

Studied by:

Approved by:

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

- This is a new requirement and quite a tough one to comply. Always try the customer for help first. They should be quite well familiar with it
- if you are not getting input from customer, you have to do the research yourself. This is a requirement of the standard

>> End of Chapter 19 <<