Chapter 9. Product Safety Related

Contents:

0) Introduction

There is only one applicable clause in this chapter. The reason why a whole chapter is devoted to this is because the Clause is not commonly misunderstood and/or poorly catered for. Many NCs have been written on this clause alone.

1) 4.4.1.2 Product Safety (IATF16949)

Clause Description-Paraphrase)

The organization shall have documented processes for the management of product-safety related products and manufacturing processes, which shall include:

a) identification by the organization of statutory and regulatory product-safety requirements;
b) customer notification of requirements in item a);
c) special approvals for design FMEA;
d) identification of product safety-related characteristics;
e) identification and controls of safety-related characteristics of product and at the point of manufacture;
f) special approval of control plans and process FMEAs;
g) reaction plans (see Section 9.1.1.1);
h) defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification;
i) training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes;
j) changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes (see ISO 9001, Section 8.3.6); k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources
l) product traceability

(Highlights of the clause)

- (Ref to old Standards) This is a totally new clause.
- The clause requires documented processes for the management of product-safety related products and manufacturing processes
- The process shall have controls ranging from planning, implementation, checking and corrective/improvement actions.

(Compliance Best Practice)

4.4.1.2 Product Safety

1. *To comply to this clause, a documented process is required.* ***See Exhibit 9-1.***
2. *The documented process must include the necessary controls stated in a) to l) of the Clause description.*

2) SIs & FAQs

SI No	IATF Clause	Description
2	**4.4.1.2 Product safety**	The organization shall have documented processes for the management of product-safety related products and manufacturing processes, which shall include but not be limited to the following, where applicable: a) – m) (…) NOTE: Special approval **of safety related requirements or documents may be required by the customer or the organization's internal processes.** ~~**is an additional approval by the function (typically the customer) that is responsible to approve such documents with safety-related content.**~~ ***Rationale for change:*** *Clarify any confusion related to special approval review for safety related requirements or documents.*

FAQ	IATF Clause	Questions and Answers
4	**4.4.1.2 Product safety**	**QUESTION:** **What is the scope of this clause? Many organizations focus on regulatory/statutory requirements of the product and do not believe they have product safety related manufacturing product or processes.** **ANSWER:** This clause focuses on product and manufacturing process characteristics that affect the safety performance of the final assembly. These characteristics may not be directly addressed in regulatory/statutory requirements, but may be defined by the customer.
13	**4.4.1.2 Product safety**	**QUESTION:** **What are the requirements regarding the levels of training and the particular criteria required to be identified in relation to product safety (4.4.1.2)?** **ANSWER:** As with all personnel competency requirements, the people assigned to specific tasks need to be competent for that task. That competence needs to include the rules and regulations associated with the task. The safety requirements in 4.4.1.2 are very specific as to what is required. The sections include, referring to IATF 16949 section 4.4.1.2: a) suppliers are expected to be aware of all statutory and regulatory requirements associated with the markets for use of the parts, as identified by the customer. The supplier needs to know where to research the regulations for all affected countries or regions. b) Customer specifics will identify any customer notification requirements; therefore, knowledge in customer specifics (which may be taught by an internal designated subject matter expert). c) The special approvals for design FMEAs would be identified in customer specifics, see item b) above. d) and e) The identification of product safety related characteristics and their controls would be defined by the customer in its definition of special characteristics and required controls. The personnel developing PFMEAs and Control Plans would need to be knowledgeable in those areas of their customer(s) documents.

FAQ	IATF Clause	Questions and Answers
13 (cont.)	**4.4.1.2 Product safety**	Each line item f) through m) can also be similarly analyzed to determine the level of training and source of that training for each requirement within the safety requirements. Since many of the requirements depend upon customer specific requirements, there is no single complete industry training on this topic. The organization needs to review the customer and regulatory requirements associated with each of its parts appropriate for the intended country of use and safety-related part characteristics. Some customers may have specific requirements regarding product safety, training, knowledge, and personnel. It is the organization's responsibility to understand their customer's specific requirements related to product safety.

3) Supplementary Notes

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

Clause	Section	Clarification Subjects
4.4.1.2	CBP	**SN9.1. Why is safety repeated in so many places in the Standard?**
4.4.1.2	CBP	**SN9.2. Isn't it repeating, when product safety is already analysed in FMEA, and Special & Critical Characteristics?**
4.4.1.2	CBP	**SN9.3. Is product safety applicable for all organizations?**
4.4.1.2	CBP	**SN9.4. How best can we do for handling safety products?**
4.4.1.2	CBP	**SN9.5. Why bring in training into safety?**
4.4.1.2	CBP	**SN9.6. Looks like Exhibit 9-1 does not have all the points given in the Clause.**

SN9.1. Why is safety repeated in so many places in the Standard?

Safety is a rising concern by governments and customers alike. It is critical requirement, and therefore should be checked thoroughly. Standards writers will naturally hunt down the relevant areas and make reminders.

SN9.2. Isn't it repeating, when product safety is already analysed in FMEA, and Special Characteristics?

For an IATF-certified organization, FMEA, risk and opportunity analyses, special & critical characteristics marking, provide a good start to capture safety-related. But they may not be have identified all. We need to take another look from another angle to exhaust the catch.

SN9.3. Is product safety applicable for all organizations?

No, some organization are not involved in safety-related products and therefore this clause does not apply to them. They can safely declare non-applicability. However, you need to be sure of special situations stated in FAQ-4. Your product may not be safety-related, but being used as a component to a safety-related end-product. Suddenly your product may be classified safety-related.

SN9.4. How best can we do for handling safety products?

If product safety applies in your case, you need to establish a procedure for this requirement. This procedure is best parked under a technical department such as Engineering, Production or QAQC. See **Exhibit 9-1** for a specimen of the Procedure. For training and competency, FAQ-13 should be taken as a guide, and list down the requirement for HR to include in the training program.

After each project that involves product safety is completed, the activities should be checked by the Product Safety Procedure.

SN9.5. Why bring in training into safety?

Any new subjects requires training, all the more critical and safety areas. Some customers may have specific requirements regarding product safety, training, knowledge, and personnel. In this new version, the compliance may include exports. See Chapter 19. It is the organization's responsibility to understand all these and include them into the QMS. HR will play a significant role in this area.

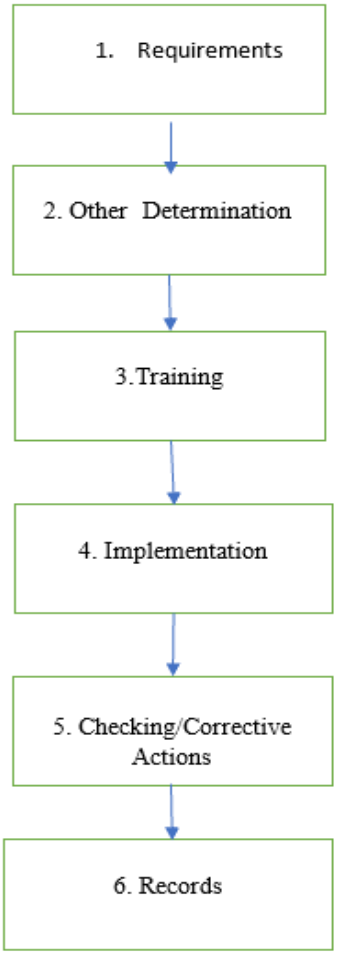
SN9.6. Looks like Exhibit 9-1 does not have all the points given in the Clause.

All points are already taken in, but may have been placed in different location. See the below where the points are found in the steps in **Exhibit 9-1**. Numeral within parenthesis is the step no of the procedure.

a) identification by the organization of statutory and regulatory product-safety requirements; (1)
b) customer notification of requirements in item a); (1)
c) special approvals for design FMEA; (1)
d) identification of product safety-related characteristics; (1)
e) identification and controls of safety-related characteristics of product and at the point of manufacture; (1)
f) special approval of control plans and process FMEAs; (1)
g) reaction plans (see Section 9.1.1.1);
h) defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification; (2)
i) training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes; (2)
j) changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes (see ISO 9001, Section 8.3.6); (1)
k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (3)
l) product traceability (1)

4) Exhibits

Exhibit 9-1. Product Safety Management

PIC	Process Flow	Description
Design /core team Core Team Core team Relevant HOD QAQC Relevant HOD/ DCC		1. Requirements • Statutory and regulatory on the relevant product safety shall be studied & understood • Customer requirements shall be clarified including: o Notification from customer o Product safety related characteristics o Special approvals on DFMEA, PFMEA, Control plans, reaction plan 2. Other determination • Determine responsibility, flow of information • Establish reaction plans and escalation procedures • Determine procedures for changes in product and process of safety-related products including approvals • Determine transfer process throughout the supply chain, on safety related requirement, including customer-designated sources • Product traceability in manufacturing and throughout the supply chain, with manufacturing lot traceability as minimum • Lessons learn process for application to new product introduction • Training needs and training materials required as identified by customer or internal 3. Training • Provide training to internal staff and to relevant external providers 4. Implementation • Implement the purchasing, manufacturing and inspection and stores • Response on problems and resolved 5. Checking • Provide checking during the process as required • The entire project shall be verified using this procedure as the check list • Any lessons learned shall be recorded for reference for new product introduction 6. Records • All relevant records shall be retained as evidence

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

- This procedure is useful to pull all the safety requirements together into a common document for reference/control
- It will also be good to prepare a checklist to verify each product-safety part under development, to ensure all steps above are followed

>>End of Chapter 9 <<