Chapter 22. Design & Development

0) Introduction

Design and Development has always been a large process. For ISO9001 you can be exempted, if you are not design responsible. For IATF, however, only product design can be exempted. Manufacturing design is always non-excluded. Even for process design alone, you are still subject to all these clauses except 8.3.2.2, 8.3.3.1, 8.3.5.1. Clause 8.3.4.3 may be included, depending on the contractual agreement. A good understanding should avoid any findings.

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

This clause has been discussed in detail in Chapter 19. Please refer.

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

This clause has been discussed in detail in Chapter 19. Please refer.

3) 8.2.3.1.3. Organization manufacturing feasibility (IATF 16949)

(Clause Description-Paraphrase)
The organization shall utilize a multidisciplinary approach to conduct an analysis to determine if it is feasible that the organization's manufacturing processes are capable of consistently producing product that meets all of the engineering and capacity requirements specified by the customer.
The organization shall conduct this feasibility analysis for any manufacturing or product technology new to the organization and for any changed manufacturing process or product design. Additionally, the organization should validate through production runs, benchmarking studies, or other appropriate methods, their ability to make product to specifications at the required rate.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, Clause 7.2.2.2 of the same title, in the previous version ISO/TS16949. The old clause was only a 1- line: "The organization shall investigate, confirm and document the manufacturing feasibility of the proposed products in the contract review process, including risk analysis"
- It is now expanded significantly to explain on the requirement, and to be feasible, the organization must meet all of the engineering and capacity requirements specified by the customer.
- Feasibility analysis is required only for any manufacturing or product technology new to the, or any changed manufacturing process or product
- Organization should validate through production runs, benchmarking studies, or other appropriate methods, their ability to make product to specifications at the required rate

*(Compliance best pra*ctice)

8.2.3.1.3. Organization manufacturing feasibility

1. *To comply with this clause, you need to conduct the feasibility study.*
2. *You can use the AIAG's "Team Feasibility Commitment "or equivalent to conduct the feasibility study. Conclude clearly whether it is feasible. See* ***Exhibit 22-1.***
3. *The last sentence of the clause "at the required rate", means capacity study is also required. See* ***Exhibit 22-2.***
4. *But the clause also said "changed manufacturing process or design change". In other words, project of existing technology or design may be exempted for the study*
5. *IATF Auditor will also look into open items in trial meetings, for follow-up actions. Make sure you have taken actions and update the records.*
6. *Validations, and any documentary approvals received (e.g. signed PSW, or 'spot' approvals, golden samples) etc. These things should be ready for audit.*

4) 8.3, 8.3.1 Design and development of products and services (ISO9001)
(Clause Description-Paraphrase)
The organization shall establish, implement and maintain a design and development process that is appropriate for the subsequent provision of products and services.

(Highlights of the clause)

- *(*Ref to old Standards). There was a similar clause, 7.3 Design and Development. in the previous version of ISO/TS16949. There were no description except a NOTE that says design can include product and manufacturing process. Design should include prevention rather than detection.

- The new clause added product and services to the title and some explanation of the purpose
- A documented process is required on design

(Compliance best practice)

8.3, 8.3.1 Design and development of products and services

1. *The clause requires a documented process. To comply, there must be a design procedure, or some written guides. See* ***Exhibit 22-3, and 22-4.***
2. *Turtle Diagram alone although is a written document, may not be acceptable as the procedure, as the information is too brief for such a complex process.*
3. *Design should include prevention rather than detection, and the message should be found in the procedure.*

5) 8.3.1 1 D&D General-Supplemental (IATF16949)

(Clause Description-Paraphrase)

The requirements of ISO 9001, Section 8.3.1, shall apply to both product and manufacturing process design and development. Additionally, they shall focus on error prevention rather than detection.

(Highlights of the clause)

- (Ref to old Standards). This was an addition NOTE to 7.3 of the previous version of ISO9001 by ISO/TS16949
- This IATF clause reminds that 8.3.1 is applicable to both product and manufacturing process. In other words, even if you are excluded from product design, this clause is still applicable.
- 'Prevention rather than detection' means preventive actions are preferred over detection.

(Compliance best practice)

8.3.1 1 D&D General-Supplemental

1. *'Prevention rather than detection' should be demonstrated in your risk analysis and design documentation*
2. *Therefore documentation such as FMEA, contexts of organization, contingency plans, and interested parties needs and expectations etc., should show prevention rather than detection, as a priority.*

6) 8.3.2 Design and development planning (ISO9001)

(Clause Description-Paraphrase)

Stages and controls for design and development depends on: (a) the nature, duration and complexity of the design and development activities; (b) the required process stages, including design reviews, (c) verification and validation activities; (d) the responsibilities and authorities involved, (e) the internal and external resource needs, (f) the need to control interfaces between persons involved, (g) involvement of customers and users, (h) the requirements for subsequent provision of products and services; (i) the level of control expected by customers and other relevant interested parties; (j) the documented information needed.

Author's note: For exact wordings, please refer to standard indicated after the clause title.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.3.1. of same title, in the previous version pf ISO/TS16949
- A lot more requirements had been added. The new element are: a) internal and external resources needed, b) and consideration to involve customers and users in the design. This is in line with the new risk-based thinking, and working with customers as a better method of satisfying customer requirement.

(Compliance best practice)

8.3.2 Design and development planning

1. *For non-automotive, written process/procedure is not a requirement. In practice, it is difficult to comply to all the requirements if they are not listed down.*
2. *A list of expected outcome /objectives (**Exhibit 22-5**) would suffice in the ISO9001 situation, where product design is involved. Otherwise it is excluded.*

7) 8.3.2.1 D&D Planning-supplemental(IATF16949)

(Clause Description-Paraphrase)

Design and development planning includes all affected stakeholders within the organization and, as appropriate, its supply chain. Examples of areas for using such a multidisciplinary approach include:
(a) project management (for example, APQP or VDA-RGA);
(b) product and manufacturing process design activities (for example, DFM and OFA), such as consideration of the use of alternative designs and manufacturing processes;
(c) development and review of product design risk analysis (FMEAs), including actions to reduce potential risks; (d) development and review of manufacturing process risk analysis (for example, FMEAs, process flows, control plans, and standardised work instructions).
NOTE A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance, and other appropriate functions.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.3.1.1 Multidisciplinary approach. The clause was short with the purpose of preparing for product realization. It particularly requires the development of special characteristics, FMEA including actions to reduce risks, and control plan. Monitoring and review required.
- Now this clause is expanded. Multidisciplinary approach is used for many other situations. See (a) to (d)
- Typical composition of a multidisciplinary team consist of design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance, and other appropriate functions.

(Compliance best practice)

8.3.2.1 D&D Planning-supplemental

1. *For IATF, only product design can be excluded. The documented process for manufacturing process design is still required.*
2. *Multifunctional approach is needed for both product and process design. Generally it means a permanent core team is required. The team is not an ad-hoc gathering of a few people, and disbanded after the design. Their responsibilities stay on until the product reaches its end-of-life.*

3. *For design documentation, you can choose APQP, RGA, VDA, Gannt chart etc, so long your customers do not object.*
4. *The items to be included are usually defined by customer, by way of a PPAP list, if available. Otherwise you use an internally defined list to guide the designed engineers.*
5. *The schedule shall correspond with customer's master schedule, such as trial and mass production dates.*
6. *D&D output can include DFM, DFA, FMEA, PFC, CP. WI, MSA, SPC, applicable functional tests etc. All the above are outputs that a IATF auditor will audit, so keep them handy.*

8) 8.3.2.2 Product Design Skills (IATF16949)

(Clause Description-Paraphrase)

Personnel with product design responsibility shall be competent to achieve design requirements and are skilled in applicable product design tools and techniques. Applicable tools and techniques shall be identified by the organization.

NOTE An example of product design skills is the application of digitized mathematically based data.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 6221 of same title, in the previous ISO/TS16949.
- Content remained the same. The new version mentioned that digitized mathematically-based data is an example of design skill, in NOTE section

(Compliance best practice)

8.3.2.2 Product Design Skills

1. *This applies to product design personnel only. They should be competent in using design software such as Catia, Autocad, Solidworks etc, as specified by customers. Keep the copies of certificates handy at the department*
2. *Software competency means formal training. Learning from friends and having a manual is not considered competent*
3. *Although not applicable to process design personnel, they should also be familiar with the design software because project may be using the drawings*
4. *Core tool competency is applicable both for process and product design personnel..*

9) 8.3.2.3 Development of product with embedded software (IATF16949)

(Clause Description-Paraphrase)

The organization shall use a process for quality assurance for their products with internally developed embedded software. A software development assessment methodology shall be utilized to assess the organization's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall retain documented information of a software development capability self-assessment. The organization shall include software development within the scope of their internal audit programme

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause
- Organization need to have a process, for quality assurance with internally developed embedded software.

- organization shall also develop a software development assessment method to check on the software development process.
- Based on risk impact to customer, records of self-assessment shall be retained
- Internal audit shall include software development, if applicable

(Compliance best practice)

8.3.2.3 Development of product with embedded software

1. *If your organization is not be involved in this, you are off the hook.*
2. *But if it is, then you need to have a process, and a software development assessment methodology, to develop, test and manage changes or upgrades.*
3. *As explain the in FAQ-15, the methodology of development a software is not different from a hardware. In the case of a purchased part with embedded software, see Chapter 24.*
4. *Embedded software is a brand new subject. A software development assessment methodology to be adopt with records (sequencing etc). This then allows for self-assessment. Priority can be set using risk and potential impact to customers as the basis. Embedded software shall be included within the scope of their QMS. If design is outsourced, the supplier shall be responsible for self-assessment. See FAQ-15.*
5. *For records, if the software design is internal, records shall be maintained internally. However, if the design is outsourced, then the records shall be maintained by the supplier.*
6. *Organization's responsibility to ensure the records are indeed retained. This can be checked during internal. For supplier, this can be done via Second Party Audit. You should bring along an IT person to assist in the audit, if you are not familiar of configuration.*

10) 8.1.2 Confidentiality (IATF16949)

The clause has been discussed in detail in Chapter 19. Please refer.

11) 8.3.3 D&D Inputs (ISO9001)

(Clause Description-Paraphrase)

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

(a) functional and performance requirements; (b) information derived from previous similar design and development activities; (c) statutory and regulatory requirements; (d) standards or codes of practice that the organization has committed to implement; (e) potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. The organization shall retain documented information on design and development inputs.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.2.2 same title, in the old version of ISO/TS1694. Previous requirement are reworded and retained.
- The new version is expanded. Point (d) & (e) are new and ending paragraph are also new.

(Compliance best practice)

8.3.3 D&D Inputs (ISO9001)

1. *See 8.3.3.1 for combined discussion.*

12) 8.3.3.1 Product Design Input (IATF16949)

(Clause Description-Paraphrase)

The organization shall identify, document, and review product design input requirements as a result of contract review. Product design input requirements include :

(a) product specifications including special characteristics,

(b) boundary and interface requirements;

(c) identification, traceability, and packaging;

(d) consideration of design alternatives;

(e) assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks, including from the feasibility analysis;

(f) targets for conformity to product requirements including preservation, reliability, durability, serviceability, health, safety, environmental, development timing, and cost;

(g) applicable statutory and regulatory requirements of the customer-identified country of destination, if provided;

(h) embedded software requirements.

The organization shall have a process to deploy information gained from previous design projects, competitive product analysis (benchmarking), supplier feedback, internal input, field data, and other relevant sources for current and future projects of a similar nature.

NOTE One approach for considering design alternatives is the use of trade-off curves.

(Highlights of the clause)

- (Ref to old Standards).There was a similar clause, 7.3.2.1 of the same title in the previous version ISO/TS16949.
- This clause is applicable only where product design is involved. Otherwise it can be omitted.
- The new clause had expanded to include some new elements in (d). (e), (g),(h). for setting targets, health, safety, environmental etc can be included where applicable.
- Need to deploy info gained from previous design projects, benchmarking, supplier feedback, internal input filed data are still required
- Total requirements are given from (a) to (h) in the clause description above.

(Compliance best practice)

8.3.3.1 Product Design Input

1. *This clause is for IATF and the earlier one 8.3.3 is for ISO9001.*
2. *First the requirements of customer shall be available before starting to design.*
3. *A few other things can be added to make the design more effect such as: a) Organization's own need, b) important experiences from previous design activities, c) compliance to relevant standards and codes of practice etc.*
4. *Ensure to get a copy of customer requirement for PPAP, so your output can be planned, and checked before submission.*
5. *There is also a need to ensure there is no conflicting D&D input. This can be easily done by listing out the input, objectives & expected output.* ***See Exhibit 22-5.***

13) 8.3.3.2 Manufacturing Process Design Input (IATF16949)

(Clause Description-Paraphrase)

The organization shall identify, document, and review manufacturing process design input requirements including:

a) product design output data including special characteristics;
b) targets for productivity, process capability, timing, and' cost;
c) manufacturing technology alternatives;
d) customer requirements, if any;
e) experience from previous developments;
f) new materials;
g) product handling and ergonomic requirements; and
h) design for manufacturing and design for assembly.

The manufacturing process design shall include the use of error-proofing methods to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.3.2.2 of same title, in the previous version of ISO/TS1694 .
- Previous requirement are found in a), b), d), e), while the new ones are c), f), g) and h)
- Ending paragraph also requires use of error-proofing methods to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered.

(Compliance best practice)

8.3.3.2 Manufacturing Process Design Input

1. *All the requirements, from a) to h) of the clause description, shall be complied*
2. *Do up a Project Schedule to manage the planning work. See* ***Exhibit 22-6***
3. *Input generally include: design objectives (output and specs summary of customer. Statutory, Regulatory and own requirements), customer schedule, lessons learned, product drawings and/or specs,*
4. *Lessons learnt are from internal manufacturing records, FMEA history etc. Some OEM customers requires continuous recording during operations. This makes things easier when developing new parts. Some other organizations would keep them in the system (hardcopy of e-copy) to be retrieved easily*
5. *If your organization is making the product for the first time, the customer should be able to furnish lessons learned*
6. *Functional tests on products are still required, but expected to be much less as compared to product design*

14) 8.3.3.3 Special Characteristics (IATF16949)

This clause has been discussed in Chapter 20. Please refer

15) Customer-designated Special Characteristics (IATF16949)

This clause has been discussed in Chapter 20. Please refer

16) 8.3.4 Design & Development Controls (ISO9001)

(Clause Description-Paraphrase)

The organization shall apply controls to the design and development process to ensure that:

a) the results to be achieved are defined;

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;
d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, 7.3.4 D&D Review, in the previous version of ISO9001.
- The old requirements are retained in b) and c) of the new clause. Items a) d) and e) have been mentioned over and over in this chapter. The presence here is just to fill up the pieces for the control concept. Note the change in title from 'review ' to 'control'.
- Compliance requires implementing a) to e)

(Compliance best practice)

8.3.4 Design & Development Controls

1. *This clause is excluded for ISO, if not design responsible. For IATF this is not fully exempted.*
2. *This is a concept clause, actual implementation will be carried out at various stages of the project. You are only required to understand the intent and ensure compliance. There is generally no need to produce any additional documentation here as evidence*

17) 8.3.4.1 Monitoring (IATF16949)

(Clause Description-Paraphrase)

Monitoring Measurements at specified stages during the design and development of products and processes shall be defined, analysed, and reported with summary results as an input to management review (see Section 9.3.2.1).

When required by the customer, measurements of the product and process development activity shall be reported to the customer at stages specified, or agreed to, by the customer.

NOTE When appropriate, these measurements may include quality risks, costs, lead times, critical paths, and other measurements.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.3.4.1.of same title, in the previous version of ISO/TS16949.
- The entire previous requirement is covered by first paragraph of the new version. Next paragraph is new, about provided information on process development activity to customers. Details shall be agreed with customer.

(Compliance best practice)

8.3.4.1 Monitoring

1. *This is a concept clause, actual implementation will be carried out by other departments, or at different stages of the project.*
2. *Updated status shall be reported to the customer if required. This is also an agenda item in the Management Review to report on this item*

18) 8.3.4.2 Design and Development Validation (IATF16949)

(Clause Description-Paraphrase)

Design and development validation shall be performed in accordance with customer requirements, including any applicable industry and governmental agency-issued regulatory standards. The timing of design and development validation shall be planned in alignment with customer-specified timing, as applicable.

Where contractually agreed with the customer, this shall include evaluation of the interaction of the organization's product, including embedded software, within the system of the final customer's product.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause 7.3.6. Design & Development Validation in the previous version of ISO/TS16949. The requirements of the old version are retained in the new version
- The new version requires D&D Development to be performed according customer, industry, statutory and regulatory requirements.
- The timing of D&D Validation shall be planned in alignment with customer-specified timing. New elements added in the last para, evaluation of interaction of program products, including embedded software in final customer product.

(Compliance best practice)

8.3.4.2 Design and Development Validation

1. *Validation is often stated on the project schedule and method prescribed by customer.*
2. *Problem often arises when 2 suppliers are involved in related parts. Example: in the case of paint supply, the paint for the car body should be same as the one for the bumpers. Otherwise possibility of different shades are very high.*
3. *Clarify such issues well ahead, or you have problem resolving validation later on*

19) 8.3.4.3 Prototype Program (IATF16949)

(Clause Description-Paraphrase)

When required by the customer, the organization shall have a prototype programme and control plan. The organization shall use, whenever possible, the same suppliers, tooling, and manufacturing processes as will be used in production.

All performance-testing activities shall be monitored for timely completion and conformity to requirements. When services are outsourced, the organization shall include the type and extent of control in the scope of its quality management system to ensure that outsourced services conform to requirements (see ISO 9001, Section 8.4).

(Highlights of the clause)

- *(Ref to old Standards). There had been similar clauses,* 7.3.6.2 of same title, in the previous version of ISO/TS16949.
- All old requirements are taken into the new clause, but reworded for better clarity.

Compliance best practice

8.3.4.3 Prototype Program

1. *Prototype program means producing the first design samples.*
2. *This is generally the responsibility of the customer, or via a specialist prototype company. However, customer may also appoint the production company to do this, due to the availability of facilities. This is generally outside the scope of manufacturing process design, and should require a separate contract.*
3. *By standard practice, you must use normal material, facilities that represent normal production conditions. You should not use specially selected items because you would have problem later, when comes to mass production*

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20) 8.3.4.4 Product Approval Process (IATF16949)

This clause has already been discussed in Chapter 21. Please refer

21) 8.3.5 D&D Outputs (ISO9001)

(Clause Description-Paraphrase)

The organization shall ensure that design and development outputs:

a) meet the input requirements;

b) are adequate for the subsequent processes for the provision of products and services;

c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.3.3 of the same title, in the old version of ISO9001.
- The old requirement are retained, except Information for purchasing has been removed.
- The new versions reads a) to d), with requirement for documented information on the output

(Compliance best practice)

8.3.5 D&D Outputs

Output should link to and meet the objectives determined at the start of the project. See ***Exhibit 22-5.***

22) 8.3.5.1 D&D Outputs-Supplemental (product) (IATF16949)

(Clause Description-Paraphrase)

The product design output shall be expressed in terms that can be verified and validated against product design input requirements. The product design output shall include but is not limited to the following, as applicable:

a) design risk analysis (FMEA);
b) reliability study results;
c) product special characteristics;
d) results of product design error-proofing, such as DFSS, DFMA, and FTA;
e) product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning & tolerancing (GD& T);
f) 2D drawings, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);
g) product design review results;
h) service diagnostic guidelines and repair and serviceability instructions;
i) service part requirements;
j) packaging and labeling requirements for shipping. NOTE Interim design outputs should include any engineering problems being resolved through a trade-off process.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.3.3.1 of the same title, in the previous version of ISO/TS16949.
- All previous requirement are retained but re-worded. More details included from a) to j). New items include: 3D, 2D, GD&T, service part requirements, packaging and labelling requirement for shipping.
- Total requirement are given in a) to j) stated in the Clause description.

(Compliance best practice)

8.3.5.1 D&D Outputs-Supplemental (product)

1. *This clause is about generating the output stated in in a) to j) of Clause description*
2. *Method/standard of tests may be decided by customer and in customer formats*
3. *Some of these tests are done by 3rd party, HQ. technical partners etc. Make sure they have ISO/IEC 17025 certification because they are considered independent labs. However HQ can be exempted from ISO/IEC17015, if they are IATF-certified and declared as remote locations to the organization. Tests they do, under the situation, are OK and within their internal lab capability*

23) 8.3.5.2 Manufacturing Process Design Output (IATF16949)

(Clause Description-Paraphrase)

The organization shall document the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. The organization shall verify the outputs against manufacturing process design input requirements. The manufacturing process design output shall include but is not limited to the following:

a) specifications and drawings;
b) special characteristics for product and manufacturing process;
c) identification of process input variables that impact characteristics;
d) tooling and equipment for production and control, including capability studies of equipment and process(es);

e) manufacturing process flow charts/layout, including linkage of product, process, and tooling; f) capacity analysis;
g) manufacturing process FMEA;
h) maintenance plans and instructions;
i) control plan (see Annex C);
j) standardised work and work instructions;
k) process approval acceptance criteria;
l) data for quality, reliability, maintainability, and measurability;
m) results of error-proofing identification and verification, as appropriate;
n) methods of rapid detection, feedback, and correction of product/manufacturing process nonconformities.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.3.3.2 of the same title, in the old version of ISO/TS16949.
- All previous requirement were retain in the new version with additional requirements in (b),(c), (d), and (f).
- Total requirement is therefore items a) to n) given in the clause description above.

(Compliance best practice)

8.3.5.2 Manufacturing Process Design Output

1. *The requirements stated in a) to n) given in the clause description is a requirement of the standard. They have to be met, even if not stated in customer PPAP. In practice, some flexibilities are given for non-essential analysis if justified. Example, due to the nature of the rubber parts, SPC is not required.*
2. *Project implementation, evidence and records shall be retained.*
3. *The results must match the requirements given in PPAP, PSW etc. You can do more, but not less. Design objectives stated must be met. Otherwise it is not considered as approved.*
4. *Approvals are generally given via PSW, a separate email, or onsite approval on meeting minutes, or samples etc. Some would give a purchase order, instead of approval, is still acceptable, although not so ideal.*

24) 8.3.6 D&D Changes (ISO9001)

(Clause Description-Paraphrase)

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organization shall retain documented information on:

a) design and development changes;
b) the results of reviews;
c) the authorization of the changes;
d) the actions taken to prevent adverse impacts.

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(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.3.7 of same title in the previous version of ISO/TS16949.
- Previous requirements are included in this new version. New requirement is to demonstrate authorization of the change, and to take actions to prevent adverse effects.

- Total requirement are therefore given in a) to d) of clause description.

Compliance best practice

8.3.6 D&D Changes

1. *Changes occur quite frequently during design stages. They have to be controlled*
2. *Use ECN form to manage changes arising from verification, validation, review or customer requests.*
3. *You can use your own ECN form if not specified otherwise.* ***Exhibit 12-12*** *is an ECN form.*

25) 8.3.6.1 D&D Changes-supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall evaluate all design changes after initial product approval, including those proposed by the organization or its suppliers,

a) for potential impact on fit, form, function, performance, and/or durability.

b) these changes shall be validated against customer requirements and approved internally, prior to production implementation.

c) If required by the customer, the organization shall obtain documented approval, or a documented waiver, from the customer prior to production implementation.

d) For products with embedded software, the organization shall document the revision level of software and hardware as part of the change control

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement
- For compliance, a) to d) above shall be implemented

(Compliance best practice)

8.3.6.1 D&D Changes-supplemental

1. *This clause is about further changes after product approval*
2. *Even after initial product approval, changes may still be required, most often coming from the customers. If this happens, mass production will be delayed.*
3. *Organization shall use ECN to control changes. See* ***Exhibit 12-12***

26) 7.5.3.2.2 Engineering Specifications (IATF16949)

This clause has already been discussed in Chapter 17. Please refer.

27) SIs & FAQs

SI Nbr	IATF Clause	Description
10 *deleted*	**8.4.2.3.1 Automotive product-related software or automotive products with embedded software**	**See SI 15, issued November 2018, effective January 2019.**

15	**3.1 Terms and definitions for the automotive industry**	**embedded software** **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").** **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.** ***Rationale for change:*** *Minimize confusion regarding embedded software and what is applicable.* *Deleted IATF 16949 FAQ 10.*

FAQ	IATF Clause	Questions and Answers
25	**8.3 Design and Development of products and services**	**QUESTION** **What constitutes product design responsibility for an organization?** **ANSWER** If an organization receives from its customer a fully defined engineering specification for the parts it is making (make to print), the organization would not be product design responsible. Where the organization does not receive a fully defined engineering specification for the parts it is making, the organization is product design responsible. In all cases, the organization is responsible for manufacturing process design.
15	**8.3.2.3 Development of products with embedded software**	**QUESTION:** **What is the acceptable method to assess a supplier's software development capability?** **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. 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). 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

28) Supplementary Notes

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

Clause	Section	Clarification Subjects
8.3.5.2	CBP	**SN22.1. Some customers are in the habit of not giving their approval, but give a P/O. Is this OK?**
8.3.2.2	CBP	**SN22.2. What are the usual problem, with external designer?**
8.3.2, 8.3.2.1	CBP	**SN22.3. Shall I do the project schedule on another document, or can I create on same page provide by customer?**

8.3.4	CBP	**SN22.4. Where are the verification, validation, and review steps in an actual customer guided PPAP?**
8.3.5, 8.3.5.1	CBP	**SN22.5. What happen if HQ is doing a functional test, but it does not have ISO/IEC 17025?**
8.3.5.2	CBP	**SN22.6. If there are some output specified for manufacturing really not available, is it a finding?**

SN22.1. Some customers are in the habit of not giving their approval, but giving a P/O instead. Is this OK?

In real situation, IATF Auditor normally accepts. But this actually is not OK. We are taking approval as a design review. P/O can be for another trial order. In a way, IATF auditors are also representing customers, and customers should do the correct thing. Breaking the rules here and there is just making the job of the IATF auditors difficult. They should play by the rules, just like everyone of us.

SN22.2. What are the usual problem, with external designers? How can we improve on this area?

External designers (remote location) are usually ignorant of the IATF requirement on design. They should be given a copy of the relevant procedure, because they will have to come under your QMS. Training shall also be provided. Otherwise they will come out quite badly in audit.

SN22.3. Shall I do the project schedule on another document, or can I create on same page provided by customer?

Either way is OK. Perhaps the second option is better, because you can refer to the customer schedule easily. Some OEM actually specify that way. **Exhibit 22-6** is one such example.

SN22.4. Where are the verification, validation, and review steps in an actual customer guided PPAP?

Some OEM visits in stages to assist the organization to complete the PPAP, so they are guiding the suppliers all the way. Verification and validation results are generated after each stage meeting. So verification and validation are found in every stage. Review however, is the trial meetings (both internal and external) conducted, including final approval.

If you are not lucky to have customers coming around so often, your design team should schedule verification, validation, and review internally, by conducted by the core team.

SN22.5. What happen if HQ is doing a functional test, but it does not have ISO/IEC 17025?

Onsite check on your HQ will have to take place by the IATF auditor. That will mean extra effort and cost. If the CB can arrange an auditor near your HQ to audit then you can save some cost. Alternatively, request your customer to issue a letter of acceptance.

SN22.6. If there are some output specified for manufacturing process design are really not available, is it a finding?

Technically yes. But you can explain to the IATF auditor, e.g. no new training and WI are required because the existing ones are applicable. IATF auditors do accept flexibilities based on the reasons given.

29) Exhibits

Exhibit 22-1.Team Feasibility Form from AIAG

TEAM FEASIBILITY COMMITMENT

Customer: _____ Date: _____

Part Number: _____ Part Name: _____

Revision Level _____

Feasibility Considerations

Our product quality planning team has considered the following questions.
The drawings and/or specifications provided have been used as a basis for analyzing the organizations ability to meet all specified requirements. All "no" answers are supported with attached comments identifying our concerns and/or proposed changes to enable the organization to meet the specified requirements.

YES	NO	CONSIDERATION
		Is product adequately defined (application requirements, etc. to enable feasibility evaluation?
		Can Engineering Performance Specifications be met as written?
		Can product be manufactured to tolerances specified on drawing?
		Can product be manufactured with process capability that meet requirements?
		Is there adequate capacity to produce product?
		Does the design allow the use of efficient material handling techniques?
		Can the product be manufactured within normal cost parameters? Abnormal cost considerations may include:
		- Costs for capital equipment?
		- Costs for tooling?
		- Alternative manufacturing methods?
		Is statistical process control required on the product?
		Is statistical process control presently used on similar products?
		Where statistical process control is used on similar products:
		- Are the processes in control and stable?
		- Does process capability meet customer requirements?

Conclusion

☐ Feasible	Product can be produced as specified with no revisions.
☐ Feasible	Changes recommended (see attached).
☐ Not Feasible	Design revision required to produce product within the specified requirements.

Approval

_____ Team Member/Title/Date

_____ Team Member/Title/Date

_____ Team Member/Title/Date

_____ Team Member/Title/Date

_____ Team Member/Title/Date

_____ Team Member/Title/Date

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

- This Team Feasibility Commitment format is taken from the AIAG PPAP Manual
- It provides a simple, systematic yet effective way to conduct a feasibility study by a multidisciplinary team
- The part on capacity which is only a 1-liner , and needs to have backup data
- The conclusion is important and yet some organizations will go through the rituals without making a conclusion.

Exhibit 22-2. Capacity Study Specimen

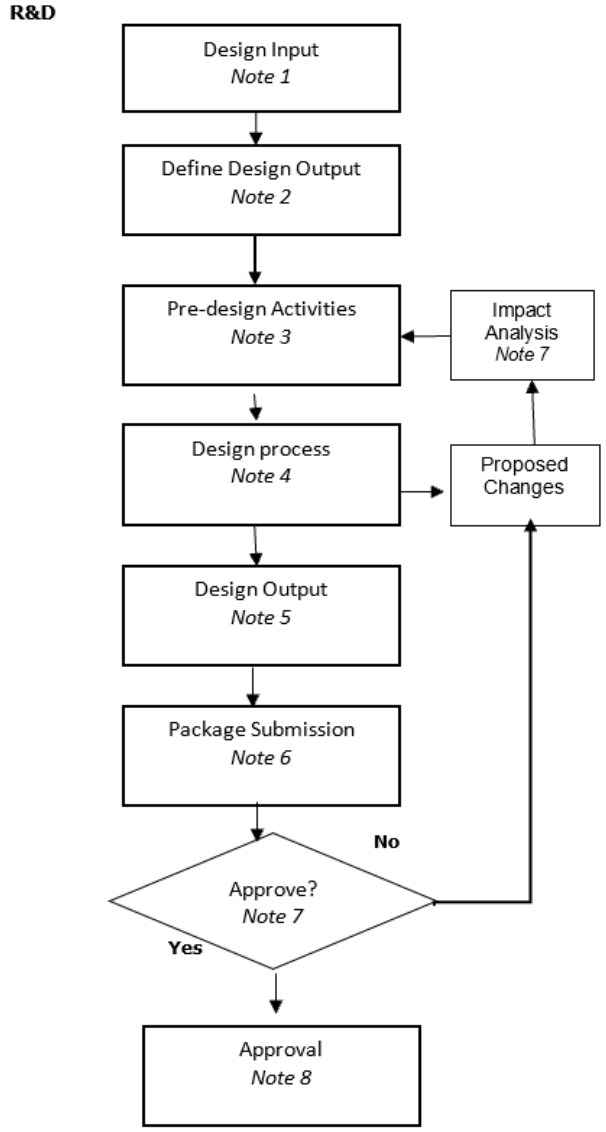
	Total	M/C 1	M/C 2	M/C 3	M/C 4	M/C 5	M/C 6	M/C 7	M/C 8
Rated capacity. pc/hr	9000	1000	1000	1000	1000	1000	1000	1500	1500
Efficiency	-	70%	75%	80%	80%	80%	80%	90%	90%
Actual Avail capacity	**7350**	**700**	**750**	**800**	**800**	**800**	**800**	**1350**	**1350**
Current Demand									
Flextronics	3400						800	1300	1300
Signmax	1400	700	700						
Celetex	1600			800	800				
Demand Total	**6400**	**700**	**700**	**800**	**800**	**0**	**800**	**1300**	**1300**
%	87%	100%	93.3	100%	100%	0%	100%	96.3%	96.3%
Potential customer									
Newbos	1000								
Conclusion: Not to accept									

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

- There are many methods for capacity planning based on nature of the products. The above case is by machine and looks complicated. Multistep manufacturing may need to assess each step to look for bottlenecks. The tendency is customer will specify their format to be used.
- The above case is rejected by customer because: a) current demand is 87% of available capacity, b)) only M/C 5 is available but can produce 800 pc, not 1000 pc as demanded by customer
- However, if the organization can justify acceptance by: a) Improving machine efficiency, b) running overtime/run an extra shift, c) Increasing capacity (buy new machines)
- The proposed idea is subject to customer acceptance. Customer also look into other factors before approving e.g. people competency, QC and maintenance capability etc during the extra hours

Exhibit 22-3 Product Design Process

Responsibility	*Activity*	*Note*



Note 1
- Input is mainly from customer such as due dates, concept drawing, lessons learned
- The design output should also be given such as drawings, samples and a list of functional, visual and dimensional characteristics
- In planning the design, aim for prevention rather than detection

Note 2
- Summarize the intended outcome in a Design Objective List
- The output shall be verified against this list

Note 3
- Usually meeting is needed with customer to clarify certain issues e.g. design language, prototype responsibility, statutory and regulatory submission package, Verification, validation and review requirement
- Minutes shall be retained

Note 4
- Design persons shall be competent for applicable designed tools
- Establish a time table and implement, observing verification, validation and review requirements
- If there are changes, risk and impact analysis is conducted before proceed. Retain risk analysis records
- Retain all changes records and associated risk analysis

Note 5
- Gather all output in the required for submission e.g. prototype, drawings 2D and 3D, DFMEA, Control Plan, functional test, visual, dimension etc.

Note 6
- Output shall be verified against objectives
- Ensure 100% compliance before submission for approval

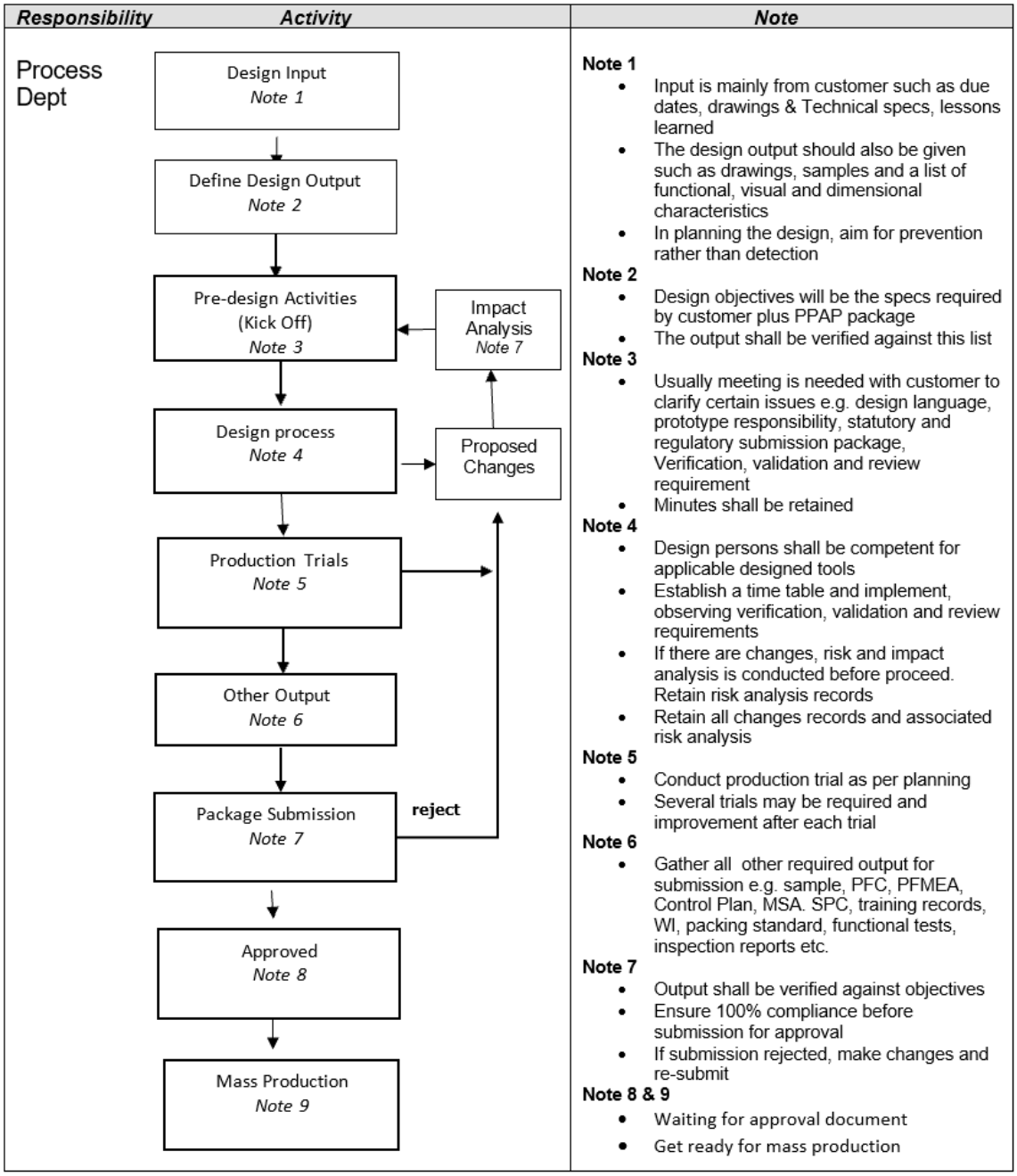
Note 7
- Follow up on approval
- There may be issues with the submission which shall be attended to

Note 8
- Submit as per customer requirement
- Follow up on approval
- Carry out any changes required

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

- This is a specimen for product design of a plastic injection moulding company
- This general process flow is a requirement, but you need to use with a PPAP or customer guide

Exhibit 22-4 Process Design Process



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

- This is a sample of manufacturing design procedure. It is needed because it is a requirement of the standard
- The flow is rather similar to a product design
- PPAP is still required to go with this general guideline

Exhibit 22-5 DD Input & Objectives

Design Objectives

Project: XRC 11000. Hinge Bracket

Design Input	Description/Objectives	(Design Output)
PPAP/PSW	Detail requirement to be followed	100% followed. OK
Drawing/Sample	Drawings to be followed, including the 'note' items	All translated into inspection dimensions. Frequency agreed with customer. OK
Customer Schedule	Customer master scheduled to be followed	Fully followed. Customer delayed by 2 months, scheduled revised and follow customer's new schedule. OK
National Codes, standards, or Statutory Requirement	None	OK
Lessons Learnt	2 points on the welding line problems. Tested solution provided by customer.	These are points and solution have been included in FMEA and control plan. OK
Other Management Requirement	None	None. OK
Function and performance Requirement	Need salt spray test 96 hours	Provides salt spray test 96 hours for every lot. OK Test results included in PPAP. OK
Potential consequences of failure due to nature of the product and what we are expected to do	None	None. OK
Any conflicting design that needs to be resolved	None	None
Feasibility study to be done	Before start of project. Engineering and quality feasibility and capacity study for 600,000 pc/year	Feasibility and capacity done, on customer format and OK by customer

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

- The above table shows an idea on criteria on the left, target/expectations in the middle, and actual output on the right. The list can be much longer than shown here. It may also include design document e.g. DFMEA, Control Plan, final drawings, functional test reports, SOD compliance tests etc
- For product design list down all customer's critical and concern points and how they are to be fulfilled. Example functional tests, dimension or other performance targets, and appearance checks as per inspection agreement. The center column shall be completed before design. **The output will only be filled before PPAP submission to ensure 100% compliance.**
- For Process design, document may include PFMEA, Control Plan, Work Instructions, Packing standard, Inspection, RoHS /SOD analysis, Inspections reports, MSA, SPC, evidence of Lessons Learnt have been verified and validated.

Exhibit 22-6. Project Schedule

Project Schedule

Project: TCSH-RR

No	Tasks	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dev
	(Customer master Schedule)												
1	---2												
2	Trail									15/9			
3	--												30/12
4	Maspro												
	(Organization Project Schedule)												
1	Drawings, data , PSW from customer												
2	Lessons learned from internal records												
3	Team Feasibility Commitment, including capacity study												
4	Process Flow Chart												
5	Design objectives												
6	PFMEA												
7	Control Plan for Pilot Trial												
8	WI, Inspection plans, packing instructions, preparation, SC management												
9	Operator Training												
10	Trial Runs (together with customer)				1/4		1/6		1/8				
11	Results compilation, FA, revised FMEA, Control Plan, revised WI, MSA, CpK, Supplier list, CSR list, shopfloor planning, checking aids, as agreed with customer												
12	PPAP submission according to customer requirement										x		
13	Approval												
14	Mass Production											1/11	

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

- This is a specimen of project planning. It is done on hardcopies. There are also customers that require you to upload onto their portals e.g. BMW
- In this example, the customer master schedule is placed on top, upon which the organization will plan theirs to meet important deadlines such as trial and mass production
- The PPAP requirements are listed down from item 1) to 14) in this particular case

>> End of Chapter 23 <<