Chapter 12 . Changes Related

Contents:

0) Introduction

There are 5 applicable clauses in this chapter, but only 3 types of changes. They are lumped together into a chapter to be given some focus attention. Clause 6.3 is totally misunderstood, and seldom seen catered for. This chapter hopes to explain on each type of change, clarify the differences, and suggest some pointers on their management..

1) 6.3. Planning of Changes (ISO9001)

(Clause Description-Paraphrase)

When changes were to take place affecting the quality management system, the changes shall be carried out in a planned manner. The organization shall consider: (a) the purpose of the changes and their potential consequences; (b) the integrity of the quality management system; (c) the availability of resources; (d) the allocation or reallocation of responsibilities and authorities.

(Interpretation & Comments)

- (Ref to old Standards) This is a totally new requirement
- It is not about changes on purchase orders, and it is not about engineering change. It is about other types of changes that may have impact on the QMS and customer satisfaction.
- Management must ensure this is done in a planned manner and considering criteria (a) to (d) of the Clause.
- This has not been a control in the past, but it is now. Control of such changes involve some planning and controls. PDCA will come in handy. Some guidelines given and you can prepare design a form to guide on this requirement. See (a) to (d) of clause description

(Compliance Best Practice)

6.3. Planning of Changes

For Planning of Changes (non-ECN type), there are 2 stages to the requirement.

1. *Stage 1 is an analysis, covering a) to d) of the clause description. Gaps shall be found to plan for change. See* ***Exhibit 12-1.***
2. *Stage 2 is the action plan to take over from Stage 1. The normal quality action plans can be used for planning. For the case in the specimen, only one form is used for both stages*

2) 8.5.6 Control of changes (ISO9001)

(Clause Description-Paraphrase) The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

(Highlights of the clause)

- (Ref to old Standards). There has been a similar clauses, 7.3.7 in the older ISO9001 standard. Note that it was parked on 'Design' before, but now it is in 'Production'
- The controls is not only about changing drawings requested by customers. It includes changes occurring in your internal departments and by your suppliers.
- Retain documented information, especially on results of the review of changes, the person(s) authorizing the change, and actions arising from reviews

(Compliance Best Practice)

8.5.6 Control of changes
See 8.5.6.1 for a combined discussion.

3) 8.5.6.1 Control of changes-supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented process to control and react to changes that impact product realization. The effects of any change, including those changes caused by the organization, the customer, or any supplier, shall be assessed. The organization shall:

a) define verification and validation activities to ensure compliance with customer requirements;
b) validate changes before implementation;
c) document the evidence of related risk analysis;
d) retain records of verification and validation. Changes, including those made at suppliers, should require a production trial run for verification of changes (such as changes to part design, manufacturing location, or manufacturing process) to validate the impact of any changes on the manufacturing process. When required by the customer, the organization shall:
e) notify the customer of any planned product realization changes after the most recent product approval;
f) obtain documented approval, prior to implementation of the change
g) complete additional verification or identification requirements, such as production trial run and new product validation.

(Highlights of the clause)

- (Ref to old Standards) This is a totally new requirement
- There are a lot of additional requirements added. Some of new requirements are:
  a) define verification and validation activities to comply with customer requirements,
  b) conduct risk analysis on the proposed change and keep records,
  c) Notify customer of intended change and obtain approval before proceeding,
  d) Validation before implementation, e) trial runs and other validation activities as required.

(Compliance Best Practice)

8.5.6.1 Control of changes-supplemental

1. *For ECN type of changes, customer format is normally used*
2. *But you should also have your own format for internal and supplier control. An example is given in* ***Exhibit 12-2.***
3. *You don't need a procedure but records of the ECN shall be retained. As this is a critical area, an ECN procedure is recommended. A specimen is given in* ***Exhibit 12-3.***
4. *For practical purpose, both 8.5.6 and 8.5.6.1 should be incorporated in the same ECN procedure.*

(4) 8.5.6.1.1 Temporary Change of Process Controls

(Clause Description-Paraphrase)

The organization shall identify, document, and maintain a list of the process controls, including inspection, measuring, test, and error-proofing devices. ~~that includes the primary process control and the approved back-up or alternate methods~~. (phrase removed by SI-11)

The requirements are:

a) The organization shall document the process that manages the use of alternate control methods. The organization shall include in this process, based on risk analysis (such as FMEA), severity, and the internal approvals to be obtained prior to production implementation of the alternate control method.

b) Before shipping product that was inspected or tested using the alternate method, if required, the organization shall obtain approval from the customer(s).

c) The organization shall maintain and periodically review a list of approved alternate process control methods that are referenced in the control plan.

d) Standardised work instructions shall be available for each alternate process control method. The organization shall review the operation of alternate process controls on a daily basis, at a minimum, to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible.

e) Example methods include but are not limited to the following:

i) daily quality focused audits (e.g., layered process audits, as applicable);

ii) daily leadership meetings. Restart verification is documented for a defined period based on severity and confirmation that all features of the error-proofing device or process are effectively reinstated.

f) The organization shall implement traceability of all product produced while any alternate process control devices or processes are being used (e.g., verification and retention of first piece and last piece from every shift).

(Highlights of the clause)

- This is a totally new requirement
- Through SI-11, IATF remove a clause (requirement for both primary and secondary methods for all controls). This waiver can save a lot of wasted hours and misery
- This clause is about temporary use alternative inspection, testing and error-proofing methods, which can impact conformity to requirement.
- Detail requirements are given in a) to f) in the clause

(Compliance Best Practice)

8.5.6.1.1 Temporary Change of Process Controls

1. *This change is about changes of process controls to some temporary or alternative measures, due to failure of primary method*
2. *Requirements for alternative or temporary process controls should best be decided and pre-approved by customer at the development stages, or during subsequent reviews.*
3. *With the temporary method pre-approved, it can kick in to replace the failure system, without delays.*
4. *Therefore, during development stage, risks on the primary monitoring and measuring methods should be studied. If any of them are problem-prone, it should be given backup, or alternative methods.*
5. *Once finalized, the backup/alternative method shall be included inside the PFC, FMEA and Control Plan.* ***Exhibit 12-5.*** *Acceptance by customers on your FMEA and Control Plan may not be sufficient. You should alert them on the temporary or alternative measures within, and request their approval.*
6. *Ad-hoc application for approval needs a lot of documentation, including risk analysis, validation data etc. It is suggested that a procedure be established, to handle such a complicated task. See* ***Exhibit 12-4.***

5) 8.2.4 Changes to requirements for products and services (ISO9001)

(Clause Description-Paraphrase)

The organization shall ensure that when the requirements for products and services are changed, the relevant documented information is amended, and that relevant persons are made aware of the changed requirements.

(Highlights of the clause)

- (Ref to old Standards) This used to be Part of Clause 7.2.2 of previous version. Now taken out as a Clause by itself
- Basically the message is the same: Changes required documented information amendments and relevant people informed of the changes

(Compliance Best Practice)

8.2.4 Changes to requirements for products and services

1. *This type of changes concerns customer purchase order changes*
2. *Make sure customers issue P/O or equivalent for purchase of your products*
3. *If there is a request for changes, it should be studied before approval. Once approved, a new P/O, or supplementary P/O shall be issued by customer*
4. *New or modified P/O shall then be taken into the system, either as hardcopy or e-copy. Inform all relevant people as soon as possible, if not immediately*
5. *Do not rely email notifications alone, you should consider to add verbal reminders, or conduct a meeting*
6. *Planner should go round checking to make sure the modification has been effected*

6) SIs & FAQs

SI Nbr	IATF Clause	Description
11	8.5.6.1.1 Temporary change of process controls	The organization shall identify, document, and maintain a list of the process controls, including inspection, measuring, test, and error-proofing devices~~, that includes the primary process control and the approved back-up or alternate methods.~~ The list of process controls shall include the primary process controls and the approved back-up or alternate methods, if back-up or alternate methods exist. ***Rationale for change:*** *Clarified that not every primary process control has a back-up or alternate method. Clarified that if a back-up or alternate method exists, that those back-up or alternate methods are included on a list maintained by the organization. It is not a requirement to have an alternative process control for every primary control.*

FAQ	IATF Clause	Questions and Answers
17	8.5.6.1.1 Temporary change of process controls	**QUESTION:** **Does there have to be an alternative process control for each primary control specified in the control plan?** **ANSWER:** No, it is not a requirement to have an alternative process control for every primary control. When introducing new products, an organization should consider the risk of the primary control potentially failing and, based on risk and severity of failure mode, decide where alternative process controls are needed. When back-up or alternate process controls are needed, then both the primary and alternative process controls should be defined in the process flow, PFMEA, control plan, and the standardized work available. For existing processes, where there is a failure in the primary process control, and no alternative process control is defined, the organization should consider risk, (e.g. FMEA) and if approved, develop standardized work for an alternative process control, implement the controls, verify effectiveness through daily management, and then revalidate when the primary control is restored. Periodically, the organization shall review instances of where alternative process controls have been used and consider this as an input to update the process flow, FMEA, and control plan. **(See SI 11)**

7) Supplementary Notes

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

Clause	Section	Clarification Subjects
6.3	CBP	**SN12.1, For 6.3 type of changes, can give some examples and how they affect QMS?**
8.5.6, 8.5.6.1	CBP	**SN12.2. Where are the pitfalls for ECN control? Can give an example?**
8.5.6.1.1	CBP	**SN12.3. Temporary Change of Process Controls. Does it really happen? Can give an example?**

8.2.4	CBP	**SN12.4. Changes to P/O. Can give example how it can go wrong?**

SN-12.1, For 6.3 type of changes, can give some examples and how they affect QMS?

Example 1:

Organization A decides to close down a 3rd Party warehouse and bring all the inventory back to the plant for warehousing and delivery. There was not much planning and management intend to 'play by ear' to deal with any issue. A host of problems cropped up, ranging from wrong delivery, late delivery, invoicing problem, stock out situation. Endless customer complaints and business losses were the results.

Example 2:

Organization B was working closely with 2 new customers for the launch of 2 range of new products. A very thorough planning was done, including provision of new production lines, machinery and facilities, re-designing of plant layout to support the new operations, and training for new technology. Sales doubled within 12 months, and yet there was very little hiccup and stress to the workforce. Good planning for changes can pay off handsomely.

SN-12.2. Where are the pitfalls for ECN control? Can give an example?

Usually the area for noncompliance is with the internal departments, ECN are not initiated for changes, and not noticed, until problem blows up. An example: new production manager was trying improve on a process to increase output. Many rounds of changes took place without proper ECN control. Output increased but rejects/returns were coming back steadily. As there is no records and no traceability, no improvement is possible. Customer complaints could not be replied. A major customer was lost as a result.

SN-12.3. Temporary Change of Process Controls. Does it really happen? Can give an example?

Yes, it happens but not so often. Example: An organization was using a customer-designed assembly station with a built in torque wrench. At the time of audit, the built-in torque wrench was out of order, and a backup manual wrench was used. This alternative method was not on the control plan. No application to customer for approval was evident. Worse, the torque wrench was not calibrated. A major NC was raised.

SN-12.4. Changes to P/O. Can give example how it can go wrong?

This is rare due to the practice is mostly in place. It can still go wrong in rare cases. Example: an organization had an order for 5 containers of a product. Before it goes into production, a new drawing came from the customer requesting to make a dimensional change. There was a communication breakdown and production went ahead without changes. QC also passed the lot because the old drawing was used for inspection. All 5 containers were return by the customer.

Exhibit 12-1. Planning for Changes

Department	Proposed Change	Reasons for Chane	Proposed by	Approved by
Delivery	Discontinue with 3P Warehouse, and bring the products back to Plant	Better control, as many complaints of late delivery, wrong delivery		

Resources needed	Actual	Impact	Action Options	Action Summary
Space	Space not enough to accommodate	Same mess like 3P warehousing now. Problem to customer	Use the empty wing we have, re-organize. Build racks	• Project shall be ready by 31 Aug 2019 • do a project plan with budget for approval by 31 Jan 2019 • Project Leader is XX • QMS shall be study and upgraded when project completed. Temp procedure to be documented.
Manpower/Competency	No one is competent in inventory management	Can totally stall the operations	Immediately start recruiting. Project Head go to Thailand to study their system	
Delivery facilities	No trucks available and driver to deliver	Cannot deliver to customers unless use outsourced contractors	Can buy truck, also can continue using the 3P warehouse's transport service. Need to study	
MRP system	MRP can handle with some upgrading	Cannot print out D/O and adjust inventories. Affect our inventory control	Upgrading as required	

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

- This change is not about ECN and it is not about customer order changes.
- It is about anything else that can affect QMS, e.g. combining of QA and QC departments

Exhibit 12-2. ECN Form Specimen

ENGINEERING CHANGE NOTICE

Requesting Subcon/Internal Dept	Request Reference	Date

Type of Change

☐ raw materials ☐ packaging materials ☐ manufacturing process	☐ equipment ☐ place of manufacture/Subcon change ☐ measuring method

Characteristics

Before	After

(Attach evidence of verification and validation, if available)

Duration

☐Temporary, From to	☐Permanent

Reason for change

Approval

Requester sign	Decision	Approver sign	Remarks
	☐Approved ☐ Not approved		

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

- This is just a specimen, not prescribed by ISO or IATF.
- In general, approval must be obtained before proceeding.
- For application to customer for approval, follow customer procedure and use customer specified forms.

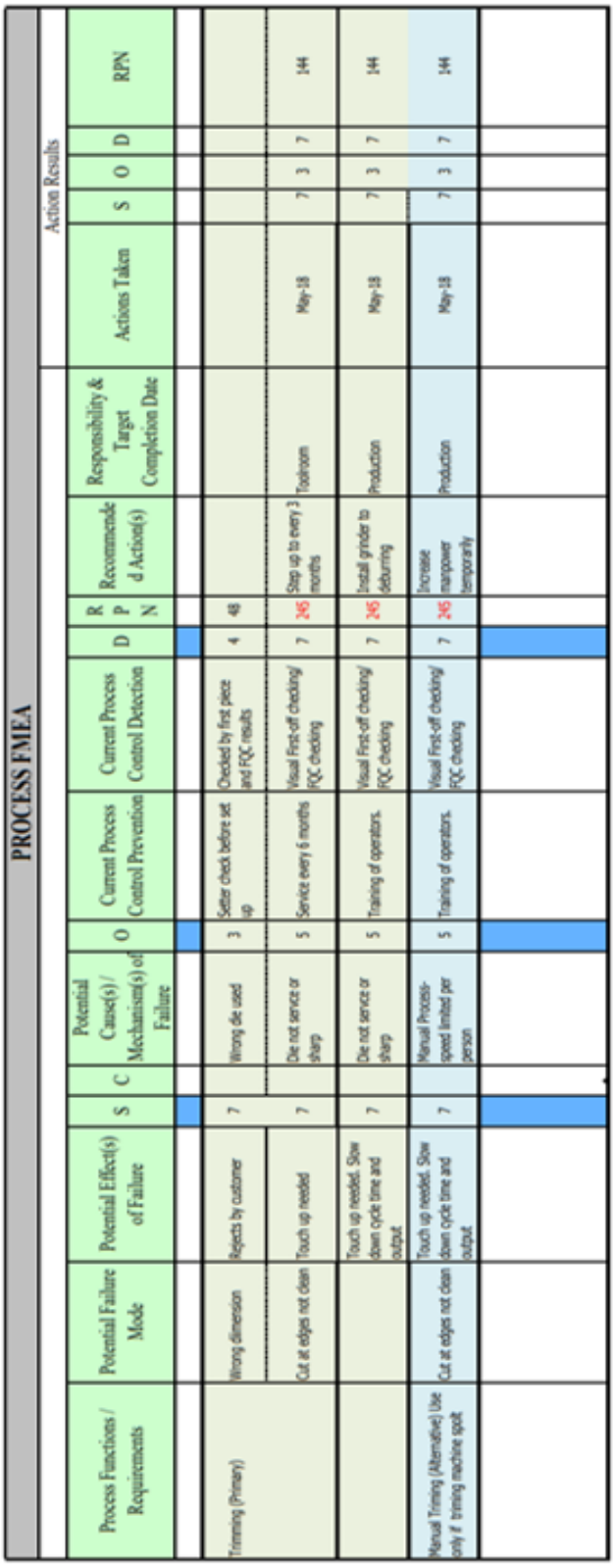
Exhibit 12-3. ECN Procedure Specimen

PIC	Flow Diagram	Key Points
Requester	9-04 (1) Engineering Change Proposal	9-04 (1) • Engineering changes refer to changes on materials, manpower, machines, processing method etc, that may impact product quality • Request for engineering changes may come from the customer, internal departments or from subcon • Internal departments and subcons change request shall via ECN, F-XXX. Customer request differs from simple email to full request with drawings
Engineering	9-04 (2) Conduct Risk Analysis	9-04 (2) • All request shall be evaluated on potential risk on product or process, using FMEA form. Validation shall be conducted. • If the change is expected to lead to a problem (s), a solution must be provided and validated before implementing. • Otherwise the request shall be rejected
Engineering	9-04 (3) Apply Documented Approval from Customer	9-04 (3) • Internal and subcon proposed changes shall be sent for pre-approval
Engineering Leads	9-04 (4) Implement change	9-04 (4) • If the impact study is satisfactory and approval obtained, implementation may proceed
	9-04 (5) Production Trial	9-04 (5) • Where requested by customer, production trial may be needed
PIC	9-04 (6) Retain Verification & Validation Records	9-04 (6) • All production trial, verification and validation record shall be retained
Planner	9-04 (7) Notification before shipment	9-04 (7) • Notification before shipment is required • Comply to all identification and traceability requirement
DCC/PIC	9-04 (8) Update and standardize relevant documentation	9-04 (8) • Update and standardize relevant documentation, which may be process flow chart, FMEA, Control Plan, Work Instructions, Inspection Sheets etc

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

- This procedure is more complicated than usual because it covers requirements of both 8.5.6 and 8.5.6.1
- The perforated brackets may not be required, depending on situation

Exhibit 12-4 Alternative method in PFMEA



PROCESS FMEA

Process Functions / Requirements	Potential Failure Mode	Potential Effect(s) of Failure	S	C	Potential Cause(s) / Mechanism(s) of Failure	O	Current Process Control Prevention	Current Process Control Detection	D	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Actions Results: Actions Taken	S	O	D	RPN
Trimming (Primary)	Wrong dimension	Rejects by customer	7		Wrong die used	3	Setter check before set up	Checked by first piece and FQC results	4	48							
	Cut at edges not clean	Touch up needed	7		Die not service or sharp	5	Service every 6 months	Visual First-off checking/ FQC checking	7	245	Step up to every 3 months	Toolroom	May-18	7	3	7	144
		Touch up needed. Slow down cycle time and output	7		Die not service or sharp	5	Training of operators.	Visual First-off checking/ FQC checking	7	245	Install grinder to deburring	Production	May-18	7	3	7	144
Manual Trimming (Alternative) Use only if trimming machine spoil	Cut at edges not clean	Touch up needed. Slow down cycle time and output	7		Manual Process-speed limited per person	5	Training of operators.	Visual First-off checking/ FQC checking	7	245	Increase manpower temporarily	Production	May-18	7	3	7	144

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

- The full PFMEA is not shown, to allow the relevant areas to be seen clearer
- This is only for PFMEA. You need to include the alternative method also in process flow chart, control plan and generate a new WI.

Exhibit 12-5. Listing the alternative method on PFMEA

PIC	Flow Chart	Description
Process owner	1. Request to use temporary verification method	Step 1 ▪ Request is normally due to the primary verification method fails, and the temporary facilities is proposed to be used
Process owner	2. Risk Analysis	Step 2 ▪ A risk analysis shall be carried out on FMEA
QA	3. customer approval	Step 3 ▪ Customer approval shall be applied with support evidences e.g. comparison results etc
Process Engineering	4. Prepare WI	Step 4 ▪ Prepare work instructions and provide training to relevant PIC
Process owners	5. Implement	Step 5 ▪ Implement the use of the temporary ▪ Implement traceability e.g. verification and retention of first and last piece from every shift
Process owner	6. Tight controls	Step 6 ▪ Provide tight surveillance throughout the period, including daily checking on the results, performance of the equipment ▪ In some cases, layered process audit may be required ▪ Reporting to top management daily on the performance ▪ Objective is still to return to the primary method as soon as possible
Process owner	7. Reinstatement	Step 7. ▪ When reinstating the primary method, verification is needed as defined in control plan Results shall be documented.
DCC	8. Update records	Step 8 ▪ Update records and standardize relevant documentation ▪ The temporary method should be included in the control plan for future application
Process Engineering	9. Periodic Review	Step 9 ▪ Set a time every year to review temporary and alternative methods on the control plans

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

- This is an example of a procedure on temporary or alternative method
- Good Management should consider to prepare requirements early e.g. during development stage or during subsequent reviews.

>> End of Chapter 12 <<