Chapter 31. Nonconformity, Corrective Action & Preventive Action

Contents:

0) Introduction

There are a few applicable clauses in this chapter. Clause 10.2.3 is almost a repeat of 10.2. Preventive is not required in ISO9001, but it is still required by IATF. The reason why a whole chapter is devoted to this is because there had been some subtle changes, which is not commonly aware and/or poorly catered for. Surprisingly after 30 years of ISO, closing methods are not well understood by many organizations. Many NCs have been written on this clause alone.

1) 10.2, 10.2.1 Nonconformity and Corrective action (ISO9001)

(Clause Description-Paraphrase)

When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:
1) take action to control and correct it;
2) deal with the consequences;
b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
1) reviewing and analysing the nonconformity;
2) determining the causes of the nonconformity;
3) determining if similar nonconformities exist, or could potentially occur;
c) implement any action needed;
d) review the effectiveness of any corrective action taken;
e) update risks and opportunities determined during planning, if necessary;
f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

(Highlights of the clause)

- (Ref to old Standards*). There had been similar clauses,* 8.5.2 Corrective Actions, in the previous version of ISO9001.
- All requirements in the previous clause are retained and included in second half of new clause.
- New requirements added are: a(2), b (containment), & b(2), c(e) & c(f)

- b(3) is seldom adopted, although not new to most people. It is about similar problem or potential problem exist, elsewhere in the organization or process etc. If so, the corrective actions can be extended (horizontal application) to these areas.

(Compliance best practice)

10.2, 10.2.1 Nonconformity and Corrective action

1. *This clause and 10.2.3 are very similar and discussed together here*
2. *The procedure on corrective actions to include the new requirements, i.e. a(2), b (containment), b(2), c(e) & c(f).*
3. *Provide a flowchart in the procedure to guide handling of nonconformity. See* ***Exhibit 31-1.***
4. *Containment shall be included as first response, if it has not been part of your corrective action procedure*
5. *The method used (why-why, fish-bone, Pareto etc) should be defined*
6. *Updating of process documents should follow, as a result of the changes (10.2.3 requirement)*
7. *Horizontal replication to similar or potential problems needs to be an added step. This is best deal with using another form, due to space constraint.* ***Exhibit 31-2.*** *Also see* ***SN-31.3 to SN-31.5*** *for explanations.*

2) 10.2.2 (Retain documented information) (ISO9001)

(Clause Description-Paraphrase)

The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action

(Highlights of the clause)

- (Ref to old Standards).This is a totally new requirement.
- It is just about the need for record, which is not a problem in most organizations

(Compliance best practice)

10.2.2 (Retain documented information)

1. *The clause required records to be retained*
2. *This is generally not an issue, as record keeping is a well-establish practice in ISO and manufacturing context*

3) 10.2.3 Problem Solving (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented process(es) for problem solving including:

a) defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);

b) containment, interim actions, and related activities necessary for control of nonconforming outputs (see ISO 9001, Section 8.7);

c) root cause analysis, methodology used, analysis, and results;

d) implementation of systemic corrective actions, including consideration of the impact on similar processes and products;

e) verification of the effectiveness of implemented corrective actions;
f) reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA, control plan). Where the customer has specific prescribed processes, tools, or systems for problem solving, the organization shall use those processes, tools, or systems unless otherwise approved by the customer.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.5.2.1 of the same title, in the previous version of ISO/TS16949.
- The old clause was a very simple statement : "The organization shall have a defined process for problem solving leading to root cause identification and Elimination"
- Point d) used to be 8.5.2.3 Corrective action impact
- The new clause is rewritten as a step-wise listing of requirements. Only real addition is is to revised document after problem solving e.g. FMEA, Control Plan etc. Revise of control plan is also mentioned in 8.5.1.1.

(Compliance best practice)

10.2.3 Problem Solving
The extra requirements here has been added to Best Practice of 10.2.1. Please refer.

4) 6.1.2.2 Preventive Actions (IATF16949)

(Clause Description-Paraphrase)

Potential nonconformities need to be determined and prevented. A process shall be established to lessen the impact of negative effects of risk including the following: (a) determining potential nonconformities and their causes; (b) evaluating the need for action; (c) determining and implementing action needed; (d) documented information of action taken; e) reviewing the effectiveness; f) utilizing lessons learned to prevent recurrence in similar processes. Preventive actions shall be appropriate to the severity of the potential issues.

(Highlights of the clause)

- (Ref to old Standards).There has been a similar clause (8.5.3) of the same title in the old version of ISO/TS16949.
- Preventive action in ISO9001, however, is no longer required.
- Method quite similar to NCR. See a) to f). notable: eval need, doc info. Action appro to severity, lessons learned

(Compliance best practice)

6.1.2.2 Preventive Actions

1. *To comply, a process shall be established (not necessarily documented), or design a form for processing such cases.*
2. *The form is quite similar to a CAR/NCR, except there is step of preliminary decision whether to take action or otherwise. See* ***Exhibit 31-3.***
3. *External happenings elsewhere can be a trigger for preventive actions. Example, if a similar organization having problem with a new material that you are also using, preventive action should kick in*
4. *You horizontal replication step in the problem-solving model (see* ***Exhibit 31-1)****, is a preventive action, but the trigger is within the organization.*

5) SIs & FAQs

No SIs & FAQs for this Chapter

6) Supplementary Notes

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

Clause	Section	Clarification Subjects
10.2.1	CBP	**SN31.1. Are there any other methods for root cause analysis besides the 3 types mentioned e.g. brain storming?**
10.2.1	CBP	**SN31.2. Horizontal application can be very wide in scanning area, how far should we go or stop?**
10.2.1	CBP	**SN31.3. Do we apply horizontal application this to internal audit? Our NCR format does not have a column for this record.**
10.2.1	CBP	**SN31.4. Do we apply application to customer audit/ customer complaint handling? The customer format does not have this column.**
10.2.1	CBP	**SN31.5. Do we apply application to CB audit? The CB format does not have this column.**
10.2.1	CBP	**SN31.6. Do we apply application every time a piece of reject occurs in the production floor?**
6.1.2.2	CBP	**SN31.7. Isn't corrective actions preventive in nature? Is it not the same as preventive action?**
6.1.2.2	CBP	**SN31.8. Instead of a new form, can I use a CA form, add the extra column needed on prelim decision?**
6.1.2.2	CBP	**SN31.9. Why Preventive action not required in ISO9001, as it looks useful?**

SN31.1. Are there any other methods for root cause analysis besides the 3 types mentioned e.g. brain storming?

The most common and accepted methods are the 3 types given. They are well understood and do not required much explanations. Any other method can be used, so long you can demonstrate that they lead logically to the root cause. And also your own people understand and know how to use the method.

SN31.2. Horizontal replication can go very wide, how far should we go or stop?

Pragmatism has to come in here. We are not into academic research but doing practical work that is keeping the organization going. Stick close to what is important and relevant, and don't wonder off too far. You should know where and when to stop. If in doubt, seek some opinion within your organization.

SN31.3. Do we apply horizontal replication to internal audit? Our NCR format does not have a column for this record.

Yes, it applies to internal audit as well. Modify your format to comply.

SN31.4. Do we apply horizontal replication to customer audit/ customer complaint handling? The customer format does not have this column.

Yes, it applies to customer audit and complaint handling. You cannot modify customer format but there is a way to comply. You can do the closing first on your own internal format, and then transfer what customer needs onto their format.

SN31.5. Do we apply application to CB audit? The CB format does not have this column.

Answer same as customer audit, please refer.

SN31.6. Do we apply horizontal replication every time a piece of reject occurs in the production floor?

No. You don't raise an NCR for a single nonconformity, unless it is a safety issue and/or expensive. You probably wait for a week or a month to review trends and the gravity of the various types of rejects, to issue an NCR. And if you do, you will complete the task right up to horizontal replication. Then you are in compliance.

SN31.7. Isn't corrective actions preventive in nature? Is it not the same as preventive action?

They are both preventive in nature, with a difference:

- Corrective Action is prevention of recurrence- problem has happened and we want to prevent it from happening again
- Preventive Action is prevention of occurrence. It may have happened elsewhere, or suspected to happen, and actions taken to prevent it. The horizontal replication is a preventive action

SN-31.8. Instead of a new preventive action form, can I use a CA format, by adding the extra column on preliminary decision?

For most cases of horizontal replication, it is the last part of the corrective action format; or as a continuation sheet (**Exhibit 35-2).**

The preventive action format (**Exhibit 35-3),** is potential nonconformity, never happened in the organization before. You take proactive action to prevent it. You need a new format. But you can use a NCR/with some modifications.

SN31.9. Why Preventive action is not required in ISO9001, as it looks useful?

The reason given by ISO is risk management analysis have fundamentally replace the need for another set of risk management analysis. IATF16949 thinks otherwise and retains the preventive actions.

7) Exhibits

xhibit 31-1. NC, CA & Problem Solving

Responsibility	Flow Diagram	Description
Receiver of notification Person-in-charge Applicable process owner	1. NC Detected 2. Containment Actions 3. Root Cause Analysis 4. Corrective Actions (permanent) 5. Verification 1 (Implemented?) 6. Verification 2 (Effective?) NG OK 7. Standardization of Associated Document 8. Horizontal Replication	Note 1 • When a nonconformance is detected. This can be detected by organization itself, or via a customer alert Note 2 • Containment shall first be taken • It is also called temporary corrective actions, or correction. An example is: If rejects produced-Stop machine, Deal with consequences Note 3 • After taking the containment, root cause analysis then begins • 3 types of analytical tools can be used: a) Why-why analysis, b)Fish bone and c) Pareto Analysis. Note 4 • The corrective actions must be link to the root cause, otherwise is it not effective Note 5 • First verification is if the actions have been implemented correctly. Note 6 • Next verification is if the effects are good. If not, go back to root cause analysis Note 7 • After the NC is effectively solved, document shall be standardized • They may include PFC, FMEA, CP, WI etc Note 8 • Branch out to verify if there is similar situation or potential situations affected by same problem • If yes, actions should be taken to apply the same concept to solve the problem

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

- In the past, both ISO and IATF were not rigid on handling methods for nonconformities
- This new revision however spelt the methods very clearly, in 10.2.1, 10.2.2 (ISO) and 10.2.3 (IATF).
- Step 8 in the flowchart above is now a requirement. In IATF it used to be called Corrective Action Impact (8.5.2.3 of the old IATF version). In Japan it is referred to as 'Yokoten'.
- It is best to use a different form to show Step 8 (Horizontal Replication) due to space constraint

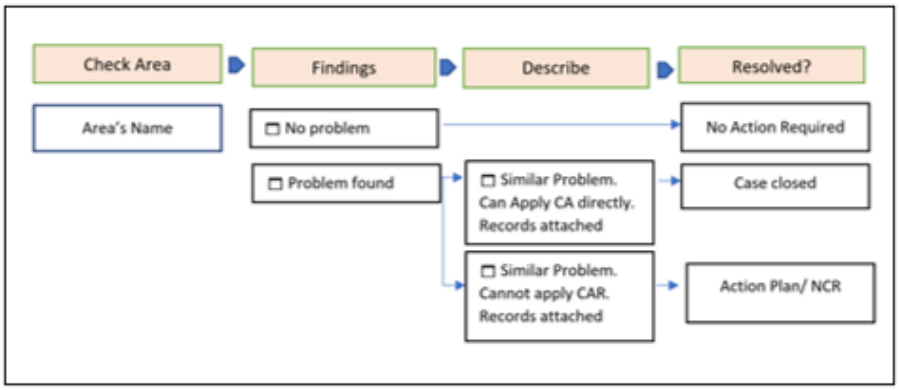
Exhibit 31-2. NC Horizontal Replication

NC Horizontal Replication

A) Nonconformance

Source of NC External Audit (Surv 1)	Date 20 Feb 2018	NCHR 2018/QMS-7	Date of NCHR 25 Mar 2018
NC Background • A new process of spray painting has been added but there is no training for the new skill required for Store control. • NC resolved, but no evidence of horizontal replication			Clause: 10.2.3. Problem Solving

A. Horizontal Replication Guide



B. Actual Checking

No	Check Area	Findings	If Finding, Describe	Resolution
1	Purchasing	Similar problem of no training	Can apply CA directly. Provided training. Implemented (3/328)	Resolved
2	Production	No problem-training provided by supplier	NA	No Action Needed
3	QAQC	No problem-requirement given by customer	NA	No Action Needed
4	Environment	Similar problem of no training	Hazardous waste PIC not inform and not taught how to handle paint wastes. Inform EMR	NCR. EMS-017/19

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

- This is only a specimen on how to complete horizontal replication. This method is simple, but effective and sufficient to comply to the requirement.
- We have seen organization putting 2 tick boxes, yes or no, (if horizontal replication done?). And they always tick yes, but without evidence. This is not acceptable.
- We have also seen very complicated methods, which are technically good, but avail no added benefits.

Exhibit 31-3. Preventive Action Request (PAR)

Preventive Action Request (PAR)

Event	Date	PAR No.
Market information	2 Nov 2018	PAR/01/2018

Potential Problem/Non-conformance Noticed

Potential Problem Description	Impact description
Heard next-door company was using a new material XYZ. End part turns yellowish after a week, and rejected by customer. Material is direct buy by customer. We have also started using the material. Our customer also same.	We may also have same problem Risk: ( ) Low ( ) Mid (x) High Actions required: (x) Yes ( ) No

(Root Cause Analysis)

Possible Root Cause	Possibility Yes/No
Wrong method (Temperature etc?) Checked SDS and verified OK	No
Environment (Wrong storage?) Material and finished parts kept under shade and inside store. Store is cooling	No
Material Problem (Inherent material problem) (No other causes detectable in our place)	Yes

(Action)

No	Actions	Due	Actual
1	Notify customer	2/11	2/11
2	Check on methods and environment of storage	3/11	2/11
3	Send confirmatory results to customer and request further advise	3/11	3/11
4	Stop production until customer provides answer	3/11	3/11
5	Purchased the old material	4/11	4/11
6	Resume production	5/11	7/11

Notes:

1. Customer advise to go back to old material, on 3/11
2. Ordered new materials and resume production
3. New agreement reached on delivery due to lost of time by 1 week

Results Verification

Results Of Action Taken is Effective? (x) Yes ( ) No

Disposition of PAR: (x) Closed out ( ) Repeat ( ) No Further Actions Needed

QMR/Date	Top Management Approval/Date

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

- This is a sample of preventive action request. You can also use the normal CAR, but make a slight change, on need for action (red circle area)
- This PAR is equivalent to horizontal replication, therefore there is no need to do horizontal replication, after closing of the PAR

>> End of Chapter 31 <<