Chapter 32. Nonconforming Outputs

Contents:

0) Introduction

There are several closely-related clauses in this chapter, on defective products and their handling. They make a very suitable cluster for discussion. Many of these clauses are new, and some not fully misunderstood and/or poorly catered for. Many NCs have been written on this clause alone. Some attention should be given.

1) 8.7, 8.7.1. Control of nonconforming outputs (ISO9001)

(Clause Description-Paraphrase)

The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. The organization shall deal with nonconforming outputs in one or more of the following ways:

a) correction;
b) segregation, containment, return or suspension of provision of products and services;
c) informing the customer;
d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.3 Control of Nonconforming Product, in the previous version of ISO9001.
- The old clause aims at preventing their unintended use or delivery of nonconforming outputs via a) eliminate the nonconformity, b) apply concession, c) stop the original intended use.
- Records: handling of the NC, including concession. Corrected NC subject to re-inspection.

- If detected after delivery or use has started, work on appropriate actions appropriate to the effects, potential effects
- New clause keeps all the previous requirement and reworded for clarity. Some new additions are similar as 10.2.1. correction; segregation, containment, return or suspension of provision, c) informing the customer; d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be re-verified when ok after rework
- Note that the formal NCP (nonconforming product), is now called NCO (nonconforming output)

(Compliance best practice)

8.7, 8.7.1. Control of nonconforming outputs

1. *This applies to the nonconforming output (NCO) detected. Any decision to use the NCO (UAI or rework) has to be approved by the customer.*
2. *If answer is negative, the NCO shall be scrapped*
3. *If the NCO can still be used, apply for concession from the customer. There is usually a customer procedure on how such applications shall be processed. Approvals should specify the quantities allowed, and temporary specs to follow.*
4. *Sometimes concession is only given for rework, and the rework method and specs shall be approved or agreed by the customer*
5. *This requires a procedure, if applicable, but many organizations do not seem to have it. See* ***Exhibit 32-1***

2) 8.7.1.1 Customer Authorization for Concession (IATF16949)

(Clause Description-Paraphrase)

The organization shall obtain customer authorization prior to further processing for "use as is" and rework (SI-9) for repair ~~dispositions~~ of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit. The organization shall maintain a record of the expiration date or quantity authorized under concession. The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession shall be properly identified on each shipping container (this applies equally to purchased product). The organization shall approve any requests from suppliers before submission to the customer.

The organization shall obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. The organization shall obtain customer authorization prior to further processing for "use as is" and rework dispositions of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit. The organization shall maintain a record of the expiration date or quantity authorized under concession. The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession shall be properly identified on each shipping container (this applies equally to purchased product). The organization shall approve any requests from suppliers before submission to the customer.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.7.1.1 Customer Authorization for Concession, in the old version of ISO/TS16949.
- The old clause is expanding on concessions.
  i) It requires organization to obtain customer concession or deviation permit before delivery whether a) use as is, b) rework, c) reuse of subcomponents,
  ii) Organization shall maintain record on expiration date or quantity authorized,
  iii) Organization must go back to original specs when concession expires,
  iv) Material shipped shall be properly identified on each shipping container,
  v) Purchased products also treated same way. Where suppliers are involve, organization must check the compliance before submission to customer.
- The new clause is just a rewording, for better clarity, and no material change in the content,
- There are a minor change on the new clause via SI-9, more on correcting grammatical errors.

(Compliance best practice)

8.7.1.1 Customer Authorization for Concession

1. *Develop a process/procedure (not mandatory) for concession management. See **Exhibit 32-1***
2. *Concession Records should be in customer format. If there is no customer format, use your own. See **Exhibit 32-5**. The records are mandatory.*

3) 8.7.1.2 Control of nonconforming product-customer-specified process (IATF16949)

(Clause Description-Paraphrase)

The organization shall comply with applicable customer-specified controls for nonconforming product(s)

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement
- If customer has a specified process on control of certain nonconformity, you need to followed.

(Compliance best practice)

8.7.1.2 Control of nonconforming product-customer-specified process

1. *This refers to special cases, specialty in nature, or repair or rework procedures developed by the customer.*
2. *When preparing a repair and a rework procedure, this clause shall be included. See **Exhibit 32-2***

4) 8.7.1.3 Control of Suspect Product (IATF16949)

(Clause Description-Paraphrase) The organization shall ensure that product with unidentified or suspect status is classified and controlled as nonconforming product. The organization shall ensure that all appropriate manufacturing personnel receive training for containment of suspect and nonconforming product.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause.
- Unidentified or suspect status is classified as nonconformities
- Relevant people shall be trained for containment of suspect and nonconforming product

(Compliance best practice)

8.7.1.3 Control of Suspect Product

1. *Material, WIP and Finished Product that have lost their labels or identifications need to be controlled as suspect. No assumption shall be taken*
2. *Onhold tags or equivalent can be used to identify the suspect. See* ***Exhibit 32-3***
3. *Sometimes the rectification is simple, consisting of tracing only, while sometimes re-inspection is needed, much depends on the case at hand.*
4. *Approval is needed from the appropriate authority to revert status of conforming from suspect.*

5) 8.7.1.4 Control of Rework Product (IATF16949)

(Clause Description-Paraphrase)

The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the rework process prior to a decision to rework the product. If required by the customer, the organization shall obtain approval from the customer prior to commencing rework of the product. The organization shall have a documented process for rework confirmation in accordance with the control plan or other relevant documented information to verify compliance. Instructions for disassembly or rework, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel. The organization shall retain documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, 8.3.2 of the same title.
- The old clause was very simple: “Instructions for rework, including re-inspection requirements, shall be accessible to and utilized by the appropriate personnel”.
- A lot new requirements added in the new clause :
    i. utilize risk analysis (such as FMEA) methodology to assess risks in the rework process prior to implementation
    ii. if required by the customer, the organization shall obtain prior approval from the customer
    iii. have a documented process for rework confirmation in accordance with the control plan or other relevant documented information to verify compliance.
    iv. Instructions for disassembly or rework, including re-inspection and traceability requirements,
    v. retain documented information on the disposition of reworked product, including quantity, disposition, disposition date, and applicable traceability information.

(Compliance best practice)

8.7.1.4 Control of Rework Product

1. *A document process is needed for this activity*
2. *There are generally 2 types of rework: a) minor touch-up e.g. on appearance, slight over-dimension problem etc., b) uncommon and rework that needs elaborated work*
3. *Type a) is usually a common occurrence, and procedure well-established. The control is the re-inspection to original specs, including functional*
4. *Type b) would need ad-hoc preparation of the rework procedure. This needs to be careful as it is more complicated than Type a). A multidisciplinary team should be used to develop the procedure and inspections.*
5. *Inspection is generally reference to control plan or other guiding document. WI for disassembly, refitting etc, and shall be prepared and made accessible to operators. Records shall be maintained.*
6. *Before implementation, risk analysis is required. Risk analysis can be carried out on a FMEA format. The risk shall be mainly on impact on the product, operations, customer's operations and operator safety.*
7. *Apply approval from customer if applicable.*

6) 8.7.1.5 Control of repair product (IATF16949)

(Clause Description-Paraphrase)

The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the repair process prior to a decision to repair the product. The organization shall obtain approval from the customer before commencing repair of the product. The organization shall have a documented process for repair confirmation in accordance with the control plan or other relevant documented information. Instructions for disassembly or repair, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel. The organization shall obtain a documented customer authorization for concession for the product to be repaired. The organization shall retain documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.

(Highlights of the clause)

- (Ref to old Standards).This is a totally requirement
- Requirement is same as rework.
- Rework and repair has a fundamental difference.
- Rework is slight deviation from the planned processes, resulting in specs not being met, but can be corrected by minor touch up or rework activities. Reference document is still based on control plan, work instruction. Some additional WI to guide on the rework. Scope of work is normally small. The work is still carried out off-line with proper tools and facilities.
- Repair generally means working to restore original specs due to damage from mishandling, wrong usage, long usage or physically damage. The scope of work varies, WI could be totally different. Inspection is on the objective of the repair. This kind of work is rare in a manufacturing organization.

(Compliance best practice)

8.7.1.5 Control of repair product

This is similar to Type b) rework in Clause 8.7.1.4. Please refer.

7) 8.7.1.6 Customer Notification (IATF16949)

(Clause Description-Paraphrase)

The organization shall immediately notify the customer(s) in the event that nonconforming product has been shipped. Initial communication shall be followed with detailed documentation of the event.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.3.3 Customer Information, in the old version of ISO001/IATF16949. It was only a 1-liner: "Customers shall be informed promptly in the event that nonconforming product has been shipped"
- Now there is a new requirement to Initial communication shall be followed with detailed documentation of the event.

(Compliance best practice)

8.7.1.6 Customer Notification

1. *This should be a CSR and stated in SQM.*
2. *Even there is no SQM, customers must be informed promptly in the event that nonconforming product has been delivered*
3. *Initial notification shall be followed with detailed documentation of the event.*

8) 8.7.1.7 Nonconforming product disposition (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented process for disposition of nonconforming product not subject to rework or repair. For product not meeting requirements, the organization shall verify that the product to be scrapped is rendered unusable prior to disposal. The organization shall not divert nonconforming product to service or other use without prior customer approval.

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, 8.7.1.7 of the same title, in the old version of ISO/TS16949. The new clause is essentially a word-for-word reproduction of the old clause.
- Documented procedure is required but seldom seen being provided.
- Important to note, that product to be scrapped is rendered unusable, to avoid diversion to other use or service part
- Organization shall verify and keep evidence

(Compliance best practice)

8.7.1.7 Nonconforming product disposition

1. *Handling of scrap disposition is a documented process. Most organizations do not have this procedure.*
2. *Due to its straightforward nature, the requirements (point 2 and 3 below) are printed on the Disposition of Scrap Form, in the case shown. See* ***Exhibit 32-5.***
3. *Organization needs to render the scrap NCO unusable before disposing. Records shall show verification of the conditions of the scrap. See* ***Exhibit 32-5***

4. *Organization shall not divert nonconforming product to service or other use without prior customer approval.*

9) 8.7.2 (relevant documented information) (ISO9001)

(Clause Description-Paraphrase)

The organization shall retain documented information that: a) describes the nonconformity; b) describes the actions taken; c) describes any concessions obtained; d) identifies the authority deciding the action in respect of the nonconformity.

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, also 8.7.2 of exact content, in the previous version of ISO9001.
- The requirement is to retain records of nonconformity, actions taken, concession and identify the authority deciding on the actions in respect of the nonconformity
- The records needed are found in 10.2.2, and 8.7.1.1

(Compliance best practice)

8.7.2 (relevant documented information)

1. *This is a repeat of 10.2.2 and 8.7.1.1, about the need to retain records*
2. *Therefore in practice, there is no special efforts to keep these records, as they are already practiced. You just need to know where to find them.*

10) SIs & FAQs

SI Nbr	IATF Clause	Description
9	**8.7.1.1 Customer authorization for concession**	The organization shall obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. The organization shall obtain customer authorization prior to further processing for "use as is" and ~~**rework**~~ **for repair (see 8.7.1.5)** ~~**dispositions**~~ of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit. ***Rationale for change:*** *Clarify requirements and eliminate contradiction in relation to customer approval associated with rework.*

FAQ	IATF Clause	Questions and Answers
11	**8.7.1.7 Nonconforming product disposition**	**QUESTION 1:** **What is the intent and requirements for "rendering unusable" prior to disposal? When and where does the "rendering unusable" of product need to occur?** **ANSWER 1:** The intent is to ensure that the product cannot find its way into the unofficial aftermarket, onto a road vehicle, or accidentally shipped to the customer. The process of rendering nonconforming product unusable, does not have to occur in the manufacturing area as long as the product is rendered unusable prior to final disposal.
11 (cont.)	**8.7.1.7 Nonconforming product disposition**	**QUESTION 2:** **How does the organization control this?** **ANSWER 2:** The organization is responsible to develop and implement a nonconforming product disposition process and verify its effectiveness. **QUESTION 3:** **Can the organization use a service provider to render the product unusable?** **ANSWER 3:** Yes, it is acceptable to contract the process of rendering the product unusable to a service provider. If a service provider is used, the organization needs to approve, and periodically verify, how the supplier is rendering the product unusable.
11 (cont.)	**8.7.1.7 Nonconforming product disposition**	**QUESTION 4:** **Does nonconforming product disposition apply only to final product or does it also apply to component/interim sub-assembly?** **ANSWER 4:** This requirement applies to the product that has gone through the part approval process and that the organization is shipping to the customer. **QUESTION 5:** **For rendering unusable, how much damage needs to be done to the nonconforming product?** **ANSWER 5:** The nonconforming product needs to be rendered unusable and unrepairable. There is no requirement for crushing or pulverizing the product into many pieces.

11) Supplementary Notes

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

Clause	Section	Clarification Subjects
8.7.1.2	CBP	**SN32.1. What is corrective action specified by customer? Can give an example?**
8.7.1.3	CBP	**SN32.2. What are suspect ? What can be the consequences? And how to handle?**
8.7.1.4 8.7.1.5	CBP	**SN32.3. *Can we have a combined procedure for rework and repair?***
8.7.1.4 8.7.1.5	CBP	**SN32.4. *What is reuse of components?***
8.7.1.7	CBP	**SN32.5. *Why and how to render a scrap unusuable?***
8.7.1.7	CBP	**SN32.6. *Can we divert to service or other use?***

8.7.1.7	CBP	**SN32.7.** ***Do we need to lock the scrap area?***

SN32.1. What is corrective action specified by customer? Can give an example?

Example: A process that originally done by the customer, but outsourced later to a supplier. Equipment, material. procedure and QAQC system are all transferred from the customer. If there is a problem, supplier goes back to the customer and supplier provides them a solution. That is customer-prescribed corrective action. And the supplier is expected to followed.

SN32.2. What are suspect ? What can be the consequences? And how to handle?

Most common one is labels missing, either fell off or a missed step by operators. Tendency is the operators will put back the label they think is correct, by looking at the shape of the material. This may suffice in reality, but it carries a major risk. The correct way is the suspects shall be first tagged on-hold, as suspect product. The follow-up actions are: a) trail backwards to identify the correct part No, b) inspect the final characteristics again to verify, c) seek approval by the relevant authority to add back the labels. If the identity cannot be established, the suspects shall be scrapped.

SN32.3. Can we have a combined procedure for rework and repair?

Yes. More so if the 2 types are quite similar. But if they are vastly different, a combined procedure can be confusing and can lead to errors. Then it would not be advisable to do so. **Exhibit 32-2** is a combined Rework & Repair Procedure.

SN32.4. What is re-use of components? Can give an example?

In some casting or moulding processes, there are the metal components used as the brackets, or conduit etc. in the article. The finished part could be rejected due to defects on casting or mouding and scrapped. But the metal part can be salvaged for re-use. They may or may not be acceptable and tests need to be done for verification. Customer would definitely need to be informed or for approval.

SN32.5. Why and how to render a scrap un-usable?

You destroy the part to the extent that it cannot be re-sold or re-used by unscrupulous parties, in particular as imitation products. Depending on the nature of the product, you may have to hack and break them to the point it cannot be used anymore.

SN32.6. Can we divert to service or other use?

Only if approved by customer. Diverting to secondary market is absolutely not permitted.

SN32.7. Do we need to lock the scrap area?

You can decide on that, as there is no requirement. For other types of industry such as medical and food, scrap rooms are under lock and key. You might want to do that to ‘wow’ your customers

12) Exhibits

Exhibit 32-1. Customer Concession Management

Responsibility	Flow Diagram	Description
QA QA/ Logistics	Note 1 Deviation detected ↓ Note 2 Apply for Concession (If applicable) ↓ Note 3 Reuse of subcomponent to be inform ↓ Note 4 Establishing Records Required ↓ Note 5 When Concession Ended ↓ Note 6 Shipping Procedure	Note 1 • Deviation detected • If deviation comes from suppliers, organization shall ensure this procedure is followed by the supplier Note 2 • If the deviation is slight and there is provision from customer to grant concession, organization shall apply for concession • Comply to customer procedure as required • Concession may be for 'Used As Is' or rework or repair • Rework and repair refer to procedure XXX • This procedure is on 'Used As Is' Note 3 • If applicable, this step will be complied to • Any subcomponents recovered for re-used shall be notified to customer Note 4 • Establish the records customer required and start recording as shipment takes places Note 5 • When concession ends, the original or superseded specs shall be followed Note 6 • Customer requirements on shipping method to be complied e.g. identified on each shipping container • Purchased product shall be handled the same way

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

- Documentation process for concession is a requirement and this is an example. Customers normally have some procedures of their own, and you need to abide
- It is also common that no concession is allowed for some customers or product lines

Exhibit 32-2. Rework and Repair Procedure

Responsibility	Flow Diagram	Description
QA Core team Production/ QA QA	Note 1 Defects for Repair or Repair ↓ Note 2 Develop Rework or Repair Procedure ↓ Note 3 Risk Analysis ↓ Note 4 Implementation & (re) Inspections ↓ Note 6 Documentation	Note 1 • When there is rework or repair is required • Inform customer for approval, where required Note 2 • Prelim rework/repair method is developed. If there is a method provided by customer, it shall be complied • WI shall also be developed e.g. for disassembly, refit, inspection etc. • These WI shall be accessible to persons doing the rework or inspections • Special identification and traceability shall also be decided before implementation Note 3 • For rework, risk analysis shall be to ensure the reworked product shall meet original specs • For repair, risk analysis shall be to ensure the repaired product conformed to control plan, and relevant WI as required • For both rework and repair, the risk analysis shall also include the impact on the operations, customer's operations and operator safety Note 4 • If approved by customer, implementation the plan • For rework, the final product shall be re-inspected to original specs • For repair, inspection shall be conducted against relevant guiding document • Delivery shall be according to customer instructions, including identification and pre-approval before delivery Note 5 • Full records shall be retained and reported to customer • Such records shall be min: quantity, disposition, disposition rate, traceability system in use etc

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

- Documented process is a requirement for rework and repair
- This is a sample that can accommodate both rework and repair

Exhibit 32-3 Onhold Label

On-hold Tag

No:	Date:
Process/ Area Found	

Discrepancy/Problem:

☐ Suspect -Missing Identification

☐ Dimension out of specs

☐ Visual inspection out of specs

☐ Functional Test Fail

Raised by :

DISPOSITION

☐ Rework/Repair
☐ Return to Vendor
☐ Return to Customer
☐ Used As Is
☐ Scrap

Corrected by:

Special Approval by
(UAI, Scarp, Etc)

Remarks

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

- This is a sample on an onhold tag. It is normally using colored paper e.g. yellow or pink
- Details are written under the relevant discrepancy. Disposition is the decision arrived on the nonconformities
- Approval authority is required for traceability. The tag is retained as records and for traceability

Concession Record

Products

Approval Ref:

Date	Defects	Expiry Date	Quantify Granted	Special ID required	Quantity shipped	Cumulative Qty	Remark

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

- Concession record is a requirement and this is a example of the recording form
- This record might be required to accompany each shipment for customer to track controls

Exhibit 32-5 Disposition of scrap Form

Nonconforming Product Disposition

Customer:

IMPORTANT REMINDRS:

- For product not meeting requirements, the organization shall verify that the product to be scrapped is rendered unusable prior to disposal.
- The organization shall not divert nonconforming product to service or other use without prior customer approval

Date	Parts Name	Qty/ Weight If applicable)	D/O No/Contractor	Verification of Disposal		
				Qty/Weight	Un-usability confirmed	Verifier

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

- The uppermost box is the documented process required by the standard. As it is only 2 sentences involved, there is no necessity to create a separate document but park them here on the form itself
- Details of disposition is recorded here. The auditor will check is whether the scrapped have been rendered unusable, and is internally verified.

>> End of Chapter 32 <<