Guidance Document for Responding to a Nonconformity Report

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Responding to a Nonconformity Report

Step 1 – Nonconformity Identification is completed by the auditor during the audit. For some international locations, the client's management signs and dates the Evidence of Company Notification field in this section. Signing this field does not restrict the client from contesting this nonconformity. Signatures can be electronic or handwritten.

Step 2 – Company Response to Nonconformity is completed by the client.
The client is responsible for providing complete responses prior to the deadline. The deadline for Step 2 is 30 days from the date the NCR was issued.

Step 2 Part A: Correction:
Client must answer all five questions (a through e) in this section:

1. Identify extent of nonconformity.
a) Describe the investigation completed to determine the answers to the next 2 questions. "None" or "N/A" are not acceptable answers. An investigation must be completed.

b) Were any nonconforming products or services involved in this nonconformity?

c) What additional negative consequences, other than nonconforming products and services, were involved in this nonconformity? Please consider the breadth and depth of the nonconformity, including whether or not it is systemic.

2. Document correction plan.
d) What was done to fix the nonconformity in the NCR and re-establish conformity? (This must be different from actions planned to avoid recurrence of it and similar problems, as listed in Corrective Action Section.)

There are three examples listed below. Each example is broken into two parts. The first part deals only with the Correction for that example. The second part deals with the Cause and Corrective Action for that example.

Example 1, 2A – This example deals only with the Correction part of the NCR:
Nonconformity: AB Corporation's Procedure X states that nonconforming product must be physically segregated from conforming product, and may not be kept in the same location. Auditor observed components identified as "scrap" on a shelf with conforming components. This does not meet the requirements of the company's internal procedure.

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The first three Correction questions help a client to determine the extent of the problem, and document their investigation.

a) Describe the investigation completed to determine the answers to the next 2 questions. “None” or “N/A” are not acceptable answers. An investigation must be completed.
All areas were checked for improperly segregated nonconforming material. 1 additional bag of nonconforming components was identified and moved to the proper location. Production Supervisor interviewed quality, production, material and packaging/shipping personnel to determine if any non-segregated, nonconforming material could have been included in a completed product. It was determined that the material in question was ignored by all and not moved or used, since it was clearly labeled as “scrap” in both cases.

b) Were any nonconforming products or services involved in this nonconformity?
No. Scrap components sat untouched in incorrect area.

c) What additional negative consequences, other than nonconforming products and services, were involved in this nonconformity? Please consider the breadth and depth of the nonconformity, including whether or not it is systemic.
Daily scrap count was incorrect for one day.

The last two questions help a client document what was done to correct/fix the nonconformity described in Step 1. This should address the nonconformity across the breadth of its system, and not address only the particular details described as evidence in the NCR. These actions are taken to eliminate a nonconformity. This is often done immediately, while the root causes and corrective actions are being determined. This step identifies and isolates all nonconforming product or data to prevent the harmful effects of the nonconformity from continuing. It continues until the problem is solved, corrective actions are taken, and the nature of the problem has been communicated to all affected parties. When taking Corrections, the following steps are usually required.

- Determine extent of undesired condition(s) / Search for other occurrences
- Fix undesired condition(s)
- Inform all parties who need to know

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d) What was done to fix the nonconformity in the NCR and re-establish conformity? (This must be different from actions planned to avoid recurrence of it and similar problems, as listed in Corrective Action Section.)
All nonconforming components were segregated per requirements. No bad final product was created as a result of this NCR.

e) What was done to fix the issues listed above in b) and c)?
Supervisor was notified of situation. Supervisor entered the scrap for the day it was found and entered a note in the system explaining the circumstances.

Example 2, 2A – This example deals only with the Correction part of the NCR:
NCR: An obsolete blueprint for product ABC was used to make product ABC.

a) Describe the investigation completed to determine the answers to the next 2 questions. "None" or "N/A" are not acceptable answers. An investigation must be completed.
The Quality Manager checked revisions of all controlled documents in use, to ensure the correct revision was being used.

b) Were any nonconforming products or services involved in this nonconformity?
Yes. 1,000 nonconforming ABC parts were created.

c) What additional negative consequences, other than nonconforming products and services, were involved in this nonconformity? Please consider the breadth and depth of the nonconformity, including whether or not it is systemic.
3 other manufacturing jobs were found to be recently completed or in process using obsolete blueprints. In addition, for each of these 3 jobs, Sales was found to be using obsolete versions of the client order.

d) What was done to fix the nonconformity in the NCR and re-establish conformity? (This must be different from actions planned to avoid recurrence of it and similar problems, as listed in Corrective Action Section.)
Manufacturing was notified. The two jobs using obsolete blueprints were stopped, and restarted using the correct revision of the blueprints. The one completed job was re-run using the correct blueprint. All nonconforming parts were destroyed. Customers were informed in the only case where this would delay the expected ship date.

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e) What was done to fix the issues listed above in b) and c)?
Sales was notified of the problem, and all aspects of the jobs initiated from incorrect revisions of client orders were reviewed to determine what other changes had been missed. For two jobs, there were no other changes. For one job, the "Ship To" address had also been revised. The "Ship To" address was updated in the system prior to shipment.

Example 3, 2A – This example deals only with the Correction part of the NCR: Nonconformity: Procedure XYZ gives incorrect instructions on how to complete a shipping label.

a) Describe the investigation completed to determine the answers to the next 2 questions. "None" or "N/A" are not acceptable answers. An investigation must be completed.
Author of Instruction XYZ was interviewed and he confirmed that this instruction was published recently, and had not been implemented, nor had training been conducted on it. No other instructions by this author have been published.

b) Were any nonconforming products or services involved in this nonconformity?
No, because instructions were not yet provided to shipping personnel.

c) What additional negative consequences, other than nonconforming products and services, were involved in this nonconformity? Please consider the breadth and depth of the nonconformity, including whether or not it is systemic.
None.

d) What was done to fix the nonconformity in the NCR and re-establish conformity? (This must be different from actions planned to avoid recurrence of it and similar problems, as listed in Corrective Action Section).
Incorrect instruction was voided in computer, and applicable personnel were informed of the issue.

e) What was done to fix the issues listed above in b) and c)?
Not applicable, since there were no nonconforming products, services or other consequences.

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Step 2 Part B: Cause Category, Cause Analysis and Corrective Action:

All Yes/No/Not Applicable questions must be answered.

1. Were all involved personnel trained and knowledgeable about their responsibilities?
2. Were all involved tools, equipment and/or software adequate and correct?
3. Was the involved environment adequate and correct?
4. Were all involved materials, parts and supplier issues adequate and correct?
5. Were the involved method, process, documents, procedures, instructions and/or design documentation adequate and correct?
6. Were the involved verification/inspection/test activities adequate and correct?

- For every "No" response, client must list the root cause and the corrective actions taken. Root cause should be determined using the "5 Whys" or other method. (An example of the "5 Whys" methodology is shown on the last page of this document.) The root cause cannot be a restatement of the cause category, but must describe the cause that allowed the problem to occur.

- For example: Cause cannot be "Tools were not adequate" because this is a restatement of category in question b).)Cause must explain why tools were inadequate.

- Planned corrective actions should eliminate or prevent the cause and/or prevent or reduce the potential for recurrence of the nonconformity. The corrective actions must be different than those in Step 2, Part A: Correction.In cases where it is not possible to totally eliminate a cause, such as a trained person making a one-off error, some action must still be taken to reduce the potential for recurrence of the cause. In some cases, fool-proofing a task, training, checklists, communication and/or reminders may be applicable corrective actions.

- A minimum of one Cause and one Action list must be completed for at least one of the cause category questions.

- Clients shall take care to avoid common errors when identifying the cause(s) of a nonconformity. These include:
  - Restating the problem as the cause
  - Assigning blame instead of identifying the cause
  - Identifying a symptom of the cause as the cause
  - Identifying an excuse and calling it the cause
  - Guessing
  - A stock answer is used in place of the cause (For example, using the same cause for every nonconformity.)

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If questions a) through f) above are all answered “Yes” or “Not Applicable,” then question g) “Was the identified Cause Category other than that listed above?” must be answered “Yes” and the client must complete the root cause and actions for this cause category.

Example 1: 2B – This example deals only with the Cause and Corrective Action parts of the NCR:

Nonconformity: AB Corporation’s Procedure X states that nonconforming product must be physically segregated from conforming product, and may not be kept in the same location. Auditor observed components identified as “scrap” on a shelf with conforming components. This does not meet the requirements of the company’s internal procedure.

1. Were all involved personnel trained and knowledgeable about their responsibilities? YES
2. Were all involved tools, equipment and/or software adequate and correct? YES
3. Was the involved environment adequate and correct? YES
4. Were all involved materials, parts and supplier issues adequate and correct? YES
5. Were the involved method, process, documents, procedures, instructions and/or design documentation adequate and correct? NO

- If no, list cause here: Instance #1 – Operator placed nonconforming material on same shelf as finished product because her Nonconforming Material Bin was missing when bad product was identified. Operator put it in a handy spot so that she would remember to put it in the bin when the bin was returned. Bin was missing because materials personnel were picking up all bins and taking them to Quality for the daily count-out and report because the Quality Manager has asked Materials to do this every day at 3 pm since Quality does the daily count-out and documents it at the end of the shift, prior to the morning supervisor’s meeting.

- If no, list actions to address cause: Materials personnel now only remove Nonconforming Material Bins after the production shift is over, and they return the Nonconforming Materials Bins prior to the next production shift. Quality does their daily count-out and documents it at the beginning of the subsequent shift. These changes have been documented in the Quality and Materials Job Sheets (#QA-7 and #M1). All associated personnel were trained in the new requirements on June 15th.New procedure was implemented on June 15th

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6.Were the involved verification/inspection/test activities adequate and correct? YES
7.Was the identified Cause Category other than that listed above? YES

- If 7) was answered yes, what was the cause? Instance #2– An unmarked bag of bad parts was found behind a pallet of good parts. The operator intentionally hid the parts because he did not want to put the bad parts in the Nonconforming Material Bin all at once, since he did not want to admit to an error that resulted in 12 bad parts at one time. He was new and feared he would be punished for the error.

- If 7) was answered yes, list actions to address cause? The area supervisor discussed this situation with the specific operator, and trained him on: how to avoid the error that caused the nonconformities; the nonconforming material procedures; and the consequences (both to the operator and the company) of not following procedures. The supervisor will continue to monitor this operator until his next review. This situation (minus the operator's identity) and the actions taken were made known to all operators and supervisors. Management stated that the consequences of hiding nonconforming material will be worse than turning it in and seeking to correct the problem.

Example 3: 2B – This example deals only with the Cause and Corrective Action parts of the NCR:

Nonconformity: Procedure XYZ gives incorrect instructions on how to complete a shipping label.

a) Were all involved personnel trained and knowledgeable about their responsibilities? No

a.If no, what was the cause? Author exceeded his authority to write an instruction, and his lack of understanding of the overall process created errors in the instructions. This was because the author was well trained and understood his own responsibilities, but did not understand the limits of his responsibilities. Process was not strong enough to prevent unauthorized instruction from being published.

b.If no, list Actions to address cause: Company-wide notification reminded all employees of the company's controlled document process, and the process for requesting a new controlled document. Controls were strengthened to prevent unauthorized work instructions from being published.

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a)Were all involved tools, equipment and/or software adequate and correct? YES

b)Was the involved environment adequate and correct? YES

c)Were all involved materials, parts and supplier issues adequate and correct? YES

d)Were the involved method, process, documents, procedures, instructions and/or design documentation adequate and correct? YES

e)Were the involved verification/inspection/test activities adequate and correct? YES

f)Was the identified Cause Category other than that listed above? NO

Step 2 Part C – Complete "Name of Client Representative Providing Response:" This is simply the name of the person completing Step 2 of the form.

Step 3 "Auditor Acceptance" (of Client's Step 2 response) and Step 4 – "Correction and Corrective Action Have Been Verified as Complete and Effective" are completed by the auditor and used to track the status of the Nonconformity Report. If no response is received by the due date, or if the client continues to fail to provide an acceptable response, Orion will take further actions. For major NCRs, suspension activities may be initiated. For minor NCRs, the NCR may be elevated to a major NCR**.**

Once the client has completed their response including correction plan, cause and corrective action plan, the auditor will review their response.

The Auditor may only accept the client's correction plan if it will effectively fix the nonconformity, re-establish conformance, and address any bad parts, services or other negative consequences. Since clients will be documenting any nonconforming parts, service or other negative consequences involved in the NCR when answering questions b and c, it will be easier for clients to determine if the actions they are describing in their answers to questions d) and e) re-establish conformity AND address the problems described in their earlier answers to b) and c). For example, if the client identified that nonconforming parts were created, but does not have any actions to deal with the nonconforming parts, the correction could not be accepted. If the correction deals with the nonconforming parts, but does not fix the nonconformity, the correction could not be accepted.

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The Auditor can only accept the client's root cause if it has gone beyond the cause category and a root cause has been identified.

The corrective action plan can only be accepted if it will eliminate or mitigate the root cause, and prevent or reduce the potential for recurrence of the nonconformity.

If any part of the response is rejected, the client will be notified with what has been rejected, and the auditor's reason for the rejection. If the response is rejected, the client must return to the NCR and edit their previous response for further consideration. Since only the plan is being reviewed at this step, there is no need to attach or send in evidence at this point.

If a corrective action audit is required to close the NCR, Orion will notify the client. This is dependent on the circumstances of the NCR(s). Corrective Action Audits are generally only done for major NCRs or when there are a large number of NCRs.

Since the evidence for most NCRs will be reviewed at an on-site audit (the next scheduled audit or Corrective Action audit), attachments are generally not needed. They are needed, however, for a situation like an off-site Corrective Action audit, or other situation where the NCR evidence is to be reviewed prior to the next audit.

Example 5-WHYs Root Cause Analysis Process

Example NCR: Required machinery was not used as required for PO 1234.

Selected Cause Category: Were all involved tools, equipment and/or software adequate and correct? – NO

5-Whys Technique to determine root cause.

- **Why wasn't required machinery used?** - The machine will not start.
- **Why?** - The battery is dead.
- **Why?** - The alternator is not functioning.
- **Why?** - The alternator belt has broken.
- **Why?** - The alternator belt was well beyond its useful service life and not replaced.
- **Why?** - The machine was not maintained according to the recommended service schedule.

The process ends when the root cause, rather than a symptom, is reached. There may be more or less than 5 "whys" using this method. Corrective Actions should directly address the root cause, to eliminate or mitigate it.

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