# Non-conformance and CAPA handling

Process Definition Document (PDD): template and worked example

*Example company (fictional): Nordvik Plast AB, an injection moulding company in Jönköping, Sweden (about 140 employees, ISO 9001 certified).*

## Document control

| Field | Value |
|---|---|
| Process name | Non-conformance and CAPA handling |
| Process owner | [Name, role] |
| Prepared by | [Name] |
| Reviewed by | [Names of the people who do the work] |
| Approved by | [Name, date] |
| Version | 1.0 (as-is) |
| Status | Draft |

## How to use this template

This is a complete process definition document (PDD) for non-conformance and CAPA handling, also called the NCR process, the non-conforming product procedure or corrective and preventive action. It describes the process as it runs today at a fictional injection moulder, with the roles, systems, steps, decisions and controls you would expect in a real quality department.

Use it as a starting point. Replace the company details, keep the sections, and walk through each step with the inspectors and engineers who handle the reports. Most companies change the severity rules that trigger a CAPA, the disposition options and the response times to customers. The structure stays the same.

- Replace the company, products and systems with yours. If you use a QMS tool instead of a database and Excel, name the module where each step happens.
- Set your own rule for when a CAPA is required in step 12. Some companies use severity, others use repeat count or cost.
- Check the percentages with real data. A quarter of NCRs usually shows how many defects are not confirmed and how many CAPAs come back for weak root cause.
- Add the customer-specific requirements you work under, such as a required 8D format or response times.
- Walk through the steps with inspectors and setters, not only quality managers. The paper tag and the weekend containment are where the gaps are.
- Keep the as-is version even after you redesign the process. It is your baseline for measuring the change.

## 1. Purpose and scope

This procedure describes how Nordvik Plast records, contains, investigates and closes product non-conformances, including corrective and preventive action (CAPA). It gives production, quality, purchasing and the warehouse one shared description of who does what, so that suspect parts never reach the customer, causes are found with evidence and actions are checked for effect. It supports the ISO 9001 certification.

### In scope

- Defects found in incoming material, in production and at final inspection
- Customer complaints, including the 8D report

- Containment, sorting, disposition, rework and scrap
- CAPA investigation, actions and effectiveness check
- Supplier corrective action requests and return orders

### Out of scope

- Supplier audits
- Tooling design changes

## 2. Process at a glance

| Item | Description |
|---|---|
| Trigger | An operator finds a suspect part, or a customer complaint arrives. |
| Starts when | The production operator places the suspect part in the red bin and calls the quality inspector. |
| Ends when | The quality manager closes the CAPA and the NCR and unblocks any remaining lots. |
| Inputs | Suspect parts and defect tag, Drawing and control plan, Process data from the moulding machine, Maintenance history, Customer complaint |
| Outputs | Non-conformance report (NCR), Blocked lot in the ERP, Disposition decision, CAPA record with root cause and actions, 8D report for complaints, Effectiveness check result |
| Volume | About 620 NCRs a year, of which about 70 lead to a CAPA |
| Working hours | Two shifts, 06:00 to 22:00, Monday to Friday. Quality staff are present 07:00 to 16:00. |

## 3. Roles and responsibilities

| Role | Responsibilities |
|---|---|
| Production Operator | Finds and reports defects, segregates suspect parts, and performs rework. |
| Quality Inspector | Confirms the defect, records the NCR, blocks the lot, decides containment and re-inspects reworked parts. |
| Quality Engineer | Reviews NCRs, sets severity, proposes dispositions, leads the CAPA investigation, writes the 8D report and checks that actions worked. |
| Production Manager | Takes part in the root cause analysis, owns the process cause and implements actions on the line. |
| Quality Manager | Approves dispositions, reviews CAPAs and closes NCRs and CAPAs. |
| Purchasing Assistant | Creates the return order in the ERP when a supplier caused the defect. |
| Customer (external) | Sends complaints, grants concessions for use-as-is parts and receives the 8D report. |
| Supplier (external) | Receives supplier corrective action requests for material defects and replies with a cause and actions. |

## 4. Systems

- Microsoft Dynamics 365 Business Central: stock, blocking of lots and purchase returns
- Access-based quality database: NCR and CAPA register
- Shared quality mailbox
- Excel: tracker for open CAPAs, reviewed in the monthly quality meeting
- Paper defect tags

## 5. Process map

**Process diagram goes here**

Draw one lane per role from section 3, the steps from section 6 in order, and a diamond for each decision in section 7.

## 6. Procedure, step by step

| # | Step | Who | What happens | System | Output |
|---|---|---|---|---|---|
| 1 | Segregate and call | Production Operator | Finds a suspect part, places it in the red bin and calls the quality inspector. It takes about 2 minutes. | Paper tag | Suspect parts segregated |
| 2 | Inspect the parts | Quality Inspector | Measures or inspects the parts against the drawing and the control plan. It takes 10 to 20 minutes. | Gauges, drawing | Defect confirmed or not |
| 3 | Confirm or release | Quality Inspector | If the defect is not confirmed, the parts go back to the line. This applies to about 20% of reports. Otherwise the inspector opens an NCR. | Quality database | Parts released, or NCR to open |
| 4 | Record the NCR | Quality Inspector | Enters the NCR with part number, lot, defect type, quantity and photos, retyping from the paper tag. It takes 10 to 15 minutes. | Quality database | NCR in the database |
| 5 | Block the lot | Quality Inspector | Blocks the affected lot in Business Central so it cannot be shipped. It takes about 5 minutes. | Business Central | Blocked lot |
| 6 | Contain and sort | Quality Inspector | Finds the last good lot and sorts or re-inspects the stock and work in progress, 100% of suspect lots. It takes 30 to 120 minutes. | Production floor | Contained stock |
| 7 | Warn the quality manager | Quality Inspector | If a delivery to the customer may be affected, informs the quality manager by phone and email the same day. This applies to about 10% of NCRs. | Phone, mailbox | Quality manager informed |
| 8 | Review and set severity | Quality Engineer | Reviews the NCR the next working day and decides the severity: minor, major or critical. | Quality database | Severity set |
| 9 | Propose a disposition | Quality Engineer | Proposes rework, scrap, use as is with customer concession, or return to supplier. It takes about 15 minutes. | Quality database | Proposed disposition |
| 10 | Approve the disposition | Quality Manager | Approves the disposition in the database. For use as is, the customer concession is requested by email first, which takes 2 to 5 days. This applies to about 8% of NCRs. | Quality database, email | Approved disposition |
| 11 | Rework or scrap | Production Operator | Performs the rework, or the warehouse scraps the parts. The inspector re-inspects reworked parts. If they fail again (about 12% of reworks), they are scrapped and the NCR is reopened for the quantity. | Production floor | Reworked or scrapped parts |
| 12 | Open a CAPA | Quality Engineer | Opens a CAPA and gathers a team for major and critical NCRs (about 11% of cases) and for every customer complaint. | Quality database | CAPA record and team |

| # | Step | Who | What happens | System | Output |
|---|---|---|---|---|---|
| 13 | Analyse the root cause | Production Manager | Runs a 5 Why or fishbone analysis with the quality engineer and the setter, using process data from the moulding machine and the maintenance history. It takes 2 to 6 hours. | Moulding machine data | Root cause analysis |
| 14 | Write the CAPA record | Quality Engineer | Writes the root cause and the actions in the CAPA record, with owners and due dates. It takes 30 to 60 minutes. | Quality database | CAPA with actions |
| 15 | Review the CAPA | Quality Manager | Reviews the CAPA. If the root cause is not supported by evidence (about 25% of CAPAs), it goes back to the engineer. Otherwise the actions are approved. | Quality database | Approved CAPA, or returned CAPA |
| 16 | Implement the actions | Production Manager | Implements the actions with the other owners, for example a changed process parameter, a work instruction update or an added inspection step. | Production floor | Actions implemented |
| 17 | Raise the supplier request | Purchasing Assistant | For supplier-caused defects, the quality engineer sends a supplier corrective action request by email and the purchasing assistant creates a return order in Business Central. | Email, Business Central | Supplier request and return order |
| 18 | Send the 8D report | Quality Engineer | For customer complaints, prepares an 8D report and sends it to the customer within 10 working days. | Email | 8D report sent |
| 19 | Check effectiveness | Quality Engineer | After 60 to 90 days, checks the NCR data for recurrence of the defect and records the result. It takes about 30 minutes. | Quality database | Effectiveness result |
| 20 | Close the CAPA and NCR | Quality Manager | Closes the CAPA and the NCR and unblocks any remaining lots in Business Central. | Quality database, Business Central | Closed NCR and CAPA |

## 7. Decision points and business rules

- Is the defect confirmed? No: release the parts back to the line (step 3).
- May a delivery to the customer be affected? Yes: tell the quality manager the same day (step 7).
- Which severity applies: minor, major or critical? Major and critical open a CAPA (steps 8 and 12).
- Which disposition: rework, scrap, use as is or return to supplier? Use as is needs a written customer concession first (steps 9 and 10).
- Do reworked parts pass re-inspection? No: scrap them and reopen the NCR (step 11).
- Is the root cause supported by evidence? No: send the CAPA back to the engineer (step 15).
- Was the defect caused by a supplier? Yes: send a supplier corrective action request and raise a return order (step 17).
- Is it a customer complaint? Yes: send an 8D report within 10 working days (step 18).

## 8. Exceptions

- Defect found after shipment (about 6% of NCRs): the process starts as a customer complaint and a sorting action is arranged at the customer site.
- Defect found on a Friday afternoon (about 15%): containment is done by the shift lead and the NCR is entered on Monday.
- Customer rejects the 8D report (about 15% of complaints): the engineer revises the analysis and resubmits.
- Supplier does not reply within 14 days (about 20% of supplier requests): the purchasing manager escalates.

## 9. Controls

- Lots under NCR are blocked in Business Central, so shipment is not possible without release by Quality.
- Segregation of duties: the person who investigates a CAPA does not approve or close it.
- Records of NCRs, dispositions and CAPA effectiveness are kept for 10 years, as required by the customer agreements and ISO 9001 clause 10.2.
- Use-as-is dispositions need a written customer concession.
- Open CAPAs are reviewed monthly.

## 10. Known issues today

- NCR data is retyped from paper defect tags into the database.
- Quality engineers are the bottleneck for next-day review, and NCRs wait when they are at customers.
- Concession requests are chased by email and phone with no tracking.
- CAPA actions are often agreed but their due dates slip without anyone noticing.
- The Excel tracker and the database differ.

## 11. RACI matrix

R = responsible (does the work), A = accountable (owns the outcome), C = consulted, I = informed.

| Activity | Operator | Inspector | Q Engineer | Prod Manager | Q Manager |
|---|---|---|---|---|---|
| Segregate and report suspect parts | R | A | | | |
| Confirm defect, record NCR, block lot | C | A/R | I | | I |
| Contain and sort suspect stock | C | A/R | I | I | |
| Set severity and propose disposition | | C | R | | A |
| Approve disposition | | I | C | | A/R |
| Rework or scrap and re-inspect | R | R | I | A | |
| Investigate root cause and write CAPA | | C | A/R | C | I |
| Implement CAPA actions | | | C | A/R | I |
| Verify effectiveness and close | | | R | C | A |

## 12. KPIs

| KPI | Definition | Target |
|---|---|---|
| NCRs per million parts | Number of NCRs opened divided by parts produced, in millions, per month. | [set] |
| Days from NCR opening to closure | Average calendar days between opening an NCR and the quality manager closing it. | [set] |
| CAPA on-time closure rate | Share of CAPAs closed on or before the agreed due date. | [set] |
| CAPAs sent back for weak root cause | Share of CAPAs returned at review because the root cause lacked evidence. Today about 25%. | [set] |
| Customer complaints and 8D response time | Complaints per quarter, and the working days from complaint to 8D report sent. The target is 10 working days. | [set] |

## 13. Revision history

| Version | Date | Author | Change |
|---|---|---|---|
| 1.0 | [date] | [name] | First as-is version |

| Version | Date | Author | Change |
|---|---|---|---|
| | | | |

*Free template from processfix.ai. You may copy and adapt it. The company in the example is fictional.*