Corrective and preventive action (CAPA)

Manual | 11 steps | 3 roles | Created Sep 2, 2026 | Updated Sep 2, 2026 | v1

How a quality team contains a nonconformance, establishes its root cause, and proves the fix actually worked.

TRIGGER

When a nonconformance is identified: a customer complaint, an internal check failure, an audit finding, or a repeated incident.

11 STEPS

1 **Reporter records what was observed, when, where, and the immediate effect, in factual terms.**

Observation, not diagnosis. "Three units shipped without the final inspection stamp" is usable; "QC was careless" closes off the investigation before it starts.

2 **Quality Manager assesses whether anything unsafe or non-conforming has reached or could reach a customer.**

Contained internally: Go to step 4: Quality Manager assigns a single named Action Owner and a target date.
Reached or could reach a customer: Go to step 3: Quality Manager takes containment action: quarantine affected stock, halt the affected process, and notify whoever must be told.

3 **Quality Manager takes containment action: quarantine affected stock, halt the affected process, and notify whoever must be told.**

Containment comes before investigation. Stop the bleeding first, then find out why, and record what was contained and when.

Contained: Go to step 4: Quality Manager assigns a single named Action Owner and a target date.

4 **Quality Manager assigns a single named Action Owner and a target date.**

One named owner. An action assigned to a team or a department is assigned to nobody.

5 **Action Owner establishes the root cause, asking why until the answer is a process or system rather than a person.**

If the answer is "someone forgot", keep going: why was forgetting possible, and why did nothing catch it? A cause you cannot design against is not a root cause.

6 **Action Owner checks whether the same or a similar issue has been raised before.**

Search the register before designing anything. A recurrence means the earlier corrective action failed, and repeating it will fail again.

First occurrence: Go to step 7: Action Owner defines the corrective action that addresses the root cause, not just the instance.
Recurrence: Go to step 11: Quality Manager escalates the recurrence, reviews why the previous action was ineffective, and treats that as the problem to solve.

7 Action Owner defines the corrective action that addresses the root cause, not just the instance.

> Retraining one person is almost never a corrective action. If the process allowed the error, the process is what has to change.

8 Action Owner implements the action and updates every procedure, form, or check the change affects.

By the agreed target date

> This is where corrective action connects to document control. A change that never reaches the written procedure has not really happened.

9 Quality Manager verifies after a defined interval that the issue has not recurred and the change is being followed as intended.

At least 30 days after implementation

> The effectiveness check is the step that separates a corrective action system from a logbook. Set the interval to something long enough for recurrence to be possible.

Effective: Go to step 10: Quality Manager closes the record with the root cause, the action taken, and the evidence of effectiveness.
Not effective: Go to step 5: Action Owner establishes the root cause, asking why until the answer is a process or system rather than a person.

10 Quality Manager closes the record with the root cause, the action taken, and the evidence of effectiveness.

> All three, or the record cannot answer anything useful later.

Closed: Ends the procedure

11 Quality Manager escalates the recurrence, reviews why the previous action was ineffective, and treats that as the problem to solve.

A recurrence is a failure of the corrective action process, not just of the process that failed. Escalating it is what stops the loop.

Escalated, reinvestigating: Go to step 5: Action Owner establishes the root cause, asking why until the answer is a process or system rather than a person.

ROLES INVOLVED

Reporter | Quality Manager | Action Owner

REVIEW CADENCE

Annually, and after any recurrence that reached a customer. A recurrence is direct evidence this procedure needs work.

Name the person accountable for this procedure before you put it into use.

CHANGE THESE BEFORE YOU USE IT

- Define your severity levels in step 2 with concrete criteria, since "could reach a customer" needs to mean something specific in your business.
- Set the effectiveness interval in step 9 per issue type. Thirty days suits a frequent process; a quarterly process needs at least two cycles.
- Name your actual register or tracking system, and make sure step 6 can actually be searched. An unsearchable register makes recurrence invisible.
- If you are certified to a standard, check the terminology it expects (nonconformity, corrective action, preventive action) and align the field names.
- This is a starting point, not certification or safety advice. Have it reviewed by whoever is accountable for your quality system.

This is a free starting point from sendabrief.com, not compliance advice. It is written to be adapted.

Source: https://sendabrief.com/templates/corrective-action-capa