Guidance Document

Correction, Corrective Action, and Preventative Action

Definitions

Correction: Action taken to eliminate detected nonconformity. A correction restores immediate control and compliance and may include product segregation, rework, or equipment/process adjustments.

Corrective Action: A specific action aimed at improving performance or outcome that is based on a root cause analysis with the intent to eliminate the cause of a non-conformity and prevent its recurrence.

Preventative Action: The action taken to eliminate the cause of a potential nonconformity or other undesirable situation in order to prevent its occurrence. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

Implementation & Audit Guidance

What does it mean?

A robust Correction, Corrective Action, and Preventative Action (CAPA) Program ensures consistent identification, containment, investigation, and resolution of food safety nonconformities.

The CAPA process:

- Ensures immediate control of nonconforming products and processes through corrections.
- Uses structured root cause analysis to identify true causes rather than symptoms.
- Implements systemic corrective actions to avoid recurrence.
- Identifies risks and negative trends early, enabling preventive actions to avoid the occurrence of future issues.
- Drives continuous improvement across the food safety management system.

Triggers for CAPA may include:

- CCP deviations
- Audit findings (internal, external, regulatory)
- Customer complaints
- Nonconforming product or packaging
- Environmental monitoring trends
- Equipment failures or near misses
- Food safety culture performance indicators

Why is it in the Code & why is it important?

The SQF Code includes requirements for corrections, corrective actions, and preventative actions because they:

1. Prevent distribution of unsafe food by ensuring immediate containment and disposition of affected products.
2. Reduce recurrence of nonconformities by addressing root causes.
3. Reduce future risks by proactively identifying and correcting potential failures.
4. Strengthen food safety culture through accountability, communication, and cross-functional problem solving.
5. Maintain audit readiness and regulatory compliance.
6. Support continuous improvement within the food safety management system.

Detected (Actual) Nonconformities

Applies to confirmed deviations such as CCP failures, mislabeling events, GMP failures, or customer complaints.

Step 1: Identification

- Detect a nonconformity through monitoring, testing, inspections, complaints, or audits.
- Document the deviation clearly, including date, time, lot, process step, and personnel involved.

Step 2: Correction

- Product Correction: Identify affected product, place on hold, evaluate impact, and determine disposition (rework, destruction, reconditioning, or release after evaluation).
- Process Correction: Adjust equipment, recalibrate sensors, revise process parameters, or pause operations until control is restored.

Step 3: Root Cause Analysis (RCA)

- Engage a cross-functional team.
- Conduct structured investigation using tools such as 5 Whys, Fishbone/Ishikawa diagrams, or FMEA (failure mode and effect analysis).
- Identify true underlying causes, not symptoms.

Step 4: Corrective Action

- Implement actions to address root causes.
- Update procedures, retrain staff, revise checklists, modify equipment, or redesign processes.

Step 5: Validation & Verification

- Confirm risk was reduced or eliminated.

Step 6: Communication

- Inform all affected personnel and leadership.
- Document training, communication, and approvals.

Step 7: Preventative Action

- Review similar products and/or processes to determine if the potential exists for the same nonconformity to occur.
- Update SOPs, modify inspection frequencies, replace deteriorating equipment, strengthen sanitation controls, or enhance training.

Continuous Improvement

Applies when trends, risk assessments, or near misses indicate a nonconformity may occur in the future.

Step 1: Identification

- Identify early warning signals through trend analysis, environmental monitoring, maintenance data, audit observations, or staff reports.

Step 2: Root Cause Analysis (RCA)

- Engage a cross-functional team.
- Conduct structured investigation using tools such as 5 Whys, Fishbone/Ishikawa diagrams, or

FMEA (failure mode and effect analysis).
- Investigate underlying causes of negative trends or near-misses.

Step 3: Preventative Action
- Implement systemic actions to eliminate causes of potential issues.
- Update SOPs, modify inspection frequencies, replace deteriorating equipment, strengthen sanitation controls, or enhance training.

Step 4: Validation & Verification
- Confirm risk was reduced or eliminated.

Step 5: Communication
- Communicate actions and results to affected departments.
- Update risk assessments to reflect risk reduction.

RIO Road to Audits (Records, Interviews, and Observations)

Records	Interviews	Observations
The following are examples of records and/or documents to assist in the implementation and review of this topic: ▪ Corrective Action Procedure ▪ Product hold logs and disposition records ▪ Process adjustment logs and maintenance reports ▪ Corrective Action Requests (CARs) and verification of effectiveness. ▪ Preventative Action Reports ▪ RCA documents and investigation forms ▪ Updated SOPs, forms, and training records ▪ Internal audit results verifying effectiveness ▪ Food safety culture risk assessment updates ▪ Management Review minutes ▪ Recall/Withdrawal Records ▪ Maintenance Work Orders ▪ Continuous Improvement Projects	The following are examples of people to interview to assist in the implementation and review of this topic: *Auditors may interview:* ▪ *QA Technicians and Hold Coordinators* ▪ *Line Operators and Supervisors* ▪ *Maintenance Technicians* ▪ *Food Safety Team Leader or SQF Practitioner* ▪ *Internal Audit Program leads* ▪ *Training Coordinators* *Sample questions:* ▪ *"How do you identify and manage nonconforming product?"* ▪ *"What tools do you use for RCA?"* ▪ *"What actions were taken to prevent this issue from recurring?"* ▪ *"What trends have you identified and how were they addressed?"*	The SQF auditor may observe the following or similar activities: Examples include: ▪ *Clear identification and segregation of nonconforming product* ▪ *Evidence of equipment adjustments or repairs* ▪ *Staff correctly performing updated procedures* ▪ *Evidence of system changes aligned with food safety culture improvements*

Additional References
- Codex Alimentarius – General Principles of Food Hygiene (CXC 1-1969)
- ISO 9000 – Quality Management Systems
- ISO 31000 – Risk Management Guidelines

- ISO 10013 – Guidelines for Quality Management System Documentation