

NON-CONFIRMITY IN ISO CERTIFICATION



What is Non-Conformity in ISO Certification?

A Non-Conformity (NC) is:

- **Non-fulfillment of a requirement** (ISO 9000 definition)
- A situation where **a process, product, or system does not meet the requirements of the ISO standard, customer requirements, or your organization's procedures.**

Examples:

- Missing calibration records
- Unapproved documents in use
- Processes not followed as per procedures

Types of Non-Conformities

- **Major NC:** Complete failure or significant risk affecting the effectiveness of the management system or compliance.
- **Minor NC:** An isolated lapse that does not significantly affect the system's ability to achieve intended results.

NC Process during ISO Audit

1. **Audit Evidence:** Auditor identifies and records evidence of non-conformity.
2. **NC Reporting:** Auditor issues a **Non-Conformity Report (NCR)** describing:
 - Requirement
 - Evidence found
 - Nature of NC (Major/Minor)
3. **Discussion:** The auditor explains the NC to the auditee for understanding.
4. **Acceptance:** The organization acknowledges and accepts the NC for action.

Corrective Action Process

After receiving an NC:

Step 1: Root Cause Analysis (RCA)

Identify **why the NC occurred** using tools like:

- 5 Whys
- Fishbone (Ishikawa) diagram

Step 2: Plan Corrective Action

Decide on actions to:

- Eliminate the root cause
- Prevent recurrence

Step 3: Implement Corrective Action

Take necessary actions (e.g., training, process revision, system updates).

Step 4: Verification

Check if the corrective action is effective and the issue has not recurred.

Step 5: Closure

The Certification Body verifies and closes the NC in the system or during the next audit.

Timeline for Corrective Actions

Certification bodies usually require:

- Submission of corrective action plan within 15-30 days of the NC issuance.
- Major NCs must be closed before certification is granted.

Benefits of Effective NC and Corrective Action Management

- Improves process reliability
- Prevents recurrence of issues
- Demonstrates commitment to continual improvement
- Strengthens compliance with ISO requirements
- Enhances customer confidence