Root Cause Analysis For Major Quality Defects

1.0 Objective & Quality Standard

The objective of this SOP is to establish a standardized, repeatable process for conducting root cause analysis (RCA) on major quality defects identified during assembly, inspection, or customer feedback. A major quality defect is defined as any non-conformance that results in rework, scrap, or customer complaint exceeding 2% of production volume for a given part or assembly. The goal is to identify the true root cause within 48 hours of defect identification and implement a permanent corrective action within 5 working days, reducing defect recurrence by at least 90%.

This procedure aligns with ISO 9001:2015 corrective action requirements and lean manufacturing principles of defect elimination. All RCA activities must be documented in the ShopDocs QA module with traceability to the original defect report.

2.0 Required Tools & Gauges

- ShopDocs QA module (digital RCA form with 5 Whys template)
- Fishbone (Ishikawa) diagram template (physical or digital)
- Defect sample or photographic evidence (minimum 3 angles)
- Production records (batch/lot number, operator, machine, date/time)
- Measurement tools relevant to the defect (calipers, micrometers, feeler gauges, torque wrench)
- Red tag labels for quarantined materials
- Whiteboard and markers for team brainstorming
- Corrective action log (digital or physical)

3.0 Safety & Material Handling

- Wear appropriate PPE (safety glasses, steel-toed boots, cut-resistant gloves) when handling defective parts that may have sharp edges or burrs.
- Quarantine all defective parts immediately using red tags to prevent accidental use in production.
- Handle defective parts with care to preserve evidence of the defect (do not alter, clean, or rework until RCA is complete).
- Ensure the RCA team meets in a quiet, distraction-free area with adequate lighting and writing surfaces.

4.0 Step-by-Step Procedure

1. Upon identification of a major quality defect, immediately quarantine all affected materials using red tags and log the defect in the ShopDocs QA module with defect description, part number, quantity, and date.

2. Assemble an RCA team consisting of the QA Manager, production supervisor, operator involved (if available), and maintenance technician (if machine-related). Assign a team leader.

3. Gather all available evidence: defective part samples, photographs, production records, measurement data, and any operator statements. Place evidence on a central table for review.

4. Define the problem statement clearly using the 5W2H method: What is the defect? Where was it found? When did it occur? Who was involved? Why is it a problem? How was it detected? How many units are affected?

5. Conduct a fishbone (Ishikawa) analysis by drawing the diagram on a whiteboard. Brainstorm potential causes under six categories: Man (operator), Machine, Material, Method, Measurement, and Environment. List all ideas without judgment.

6. Prioritize the most likely causes from the fishbone diagram using a simple voting or consensus method. Select the top 3-5 potential root causes for deeper investigation.

7. Apply the 5 Whys technique to each prioritized cause. Ask 'Why?' five times (or until the root cause is identified) and document each answer. For example: Why is the gap too large? Because the hinge was misaligned. Why was the hinge misaligned? Because the jig was worn. Why was the jig worn? Because it was not replaced per PM schedule.

8. Verify the identified root cause by replicating the defect under controlled conditions (if possible) or by reviewing historical data. If the root cause cannot be replicated, consider additional data collection or a controlled experiment.

9. Develop a permanent corrective action plan that addresses the root cause. The plan must include: what will be done, who is responsible, the implementation date, and how effectiveness will be verified. Examples: update PM schedule, retrain operator, replace tooling, revise work instruction.

10. Implement the corrective action immediately. Update relevant documentation (SOPs, work instructions, PM schedules) and train all affected personnel within 24 hours of implementation.

11. Monitor the effectiveness of the corrective action for a minimum of 2 weeks or 100 production units (whichever is longer). Collect data on defect recurrence and compare to baseline.

12. If the corrective action is effective (defect recurrence reduced by 90% or more), close the RCA in the ShopDocs QA module with a summary of findings and actions taken. If not effective, repeat steps 5-11 with additional data.

5.0 Verification & Defect Reporting

1. Verify that all defective units have been quarantined and red-tagged before any rework or disposition. No defective unit shall be reworked without QA approval.

2. Document the root cause and corrective action in the ShopDocs QA module, including the fishbone diagram and 5 Whys analysis as attachments.

3. If the root cause is not identified within 48 hours, escalate to the Plant Manager for additional resources or a formal kaizen event.

4. All out-of-tolerance defects and their root causes must be reviewed in the weekly quality meeting. Recurring defects (more than 2 occurrences in 30 days) trigger a mandatory process audit.

5. Log all corrective actions in the corrective action log with status (open, in progress, closed) and update weekly.