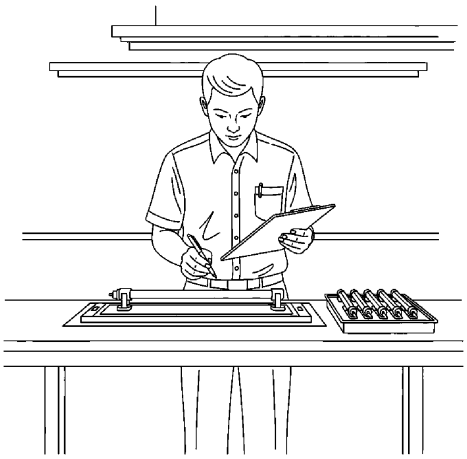
NICHE-SEARCH

WORKSHEET 6 OF 9

Root-Cause Analysis Fishbone — Chronic Defect

For defects that have appeared in three or more consecutive monthly Pareto reports without permanent resolution. Run as a 90-minute cross-functional session.



Complementary worksheet for
Quality Control Systems
by Ibrahim Anwar

SECTION 1

What This Is For

A defect that survives three consecutive monthly Pareto reports is not a production problem. It is a system problem — the corrective actions applied so far only reached the symptom. The fishbone worksheet is the tool for the 90-minute session that opens up all six cause categories at once, forces the team to supply data references rather than opinions, and ends with a verification plan, not just a list of suspects.

This sheet does not replace the 5 Whys. It extends it. The 5 Whys works when the cause chain is linear. The fishbone works when multiple factors from different categories (machine calibration drift, operator shift practice, incoming material variability) may be contributing simultaneously. Three months of the same defect in the Pareto report is the clearest signal that the cause is not linear.

SECTION 2

Benefits

What you get when you actually run this worksheet on a real situation:

- Structures a cross-functional session so that all six cause categories are examined — not just the ones the QC team suspects — before the investigation closes.
- The evidence column enforces data discipline: every suspected factor must be linked to an NCR reference, a calibration log date, or a shift record. Opinion-only factors are automatically de-prioritized.
- Produces two or three CAPA candidates with data support, not a list of ten action items that no one resources or closes.
- The verification gate before the session ends names a person, a data source, and a return date for the top-ranked factor — converting the fishbone from a brainstorm into an investigation with accountability.
- Generates documentation the CAPA system needs: problem statement, causal factors examined, evidence, likelihood assessment, and verification plan in one sheet.

SECTION 3

Framework To Use

— Six-M Cause Inventory

Ishikawa's six cause categories applied systematically — every potential factor mapped before any factor is ranked.

Six-M Category Guide

Category	What to Ask	Data Source
Man	Training level, operator substitution, shift handover quality, fatigue pattern	Training register, shift roster, IPQC by-operator breakdown
Machine	Last calibration date, known wear, parameter drift, maintenance schedule adherence	Calibration log, maintenance records, machine parameter log
Method	SOP exists and current? SOP followed as written? Any recent process change?	SOP revision date, shift observation, change control records
Material	IQC result for the lot used, supplier change, storage conditions, substitute material	IQC receiving log, supplier change record, warehouse temp log
Measurement	Correct tool used? Tool within calibration date? Tolerance defined in writing?	Calibration log, inspection SOP, tolerance spec sheet
Mother Nature	Temperature/humidity during the batch, cleanliness, power supply quality	Environment log, shift record, maintenance report

SECTION 4

How To Use

Follow these steps in order. Each one builds on the previous.

1. Before the session: pull three months of NCR records for the chronic defect type. Calculate which shift, which operator group, and which material lot the defect is most concentrated in. This data brief goes to all session participants before they arrive.

2. State the problem at the fish head in one specific sentence: 'Seal failure rate averaging 4.2% per month for the past three months, concentrated in afternoon shift, packaging line 2.' Specific problem statements produce specific investigations.

3. Work through each of the six cause categories systematically. For each category, ask the question from the framework above. Write potential factors in the Potential Factor column — do not rank or filter during this phase.

4. For each potential factor: fill the Evidence column with the specific data source that would confirm or deny it. If no data source exists, write 'no data — needs collection' and mark Likelihood Low until data is gathered.

5. After all factors are listed, assign Likelihood: High (data reference exists and points in this direction), Medium (plausible, partial data), or Low (plausible but no supporting data or evidence contradicts).

6. Identify the two or three factors with both High likelihood and a data reference. These are the CAPA candidates. Write one CAPA number for each before the session ends.

7. Verification gate: for the top-ranked factor, state what data would confirm or disprove it, who will collect it, and what date they report back. Write this in the margin or on a separate sticky. The session does not close without this step.

SECTION 5

Example Use

A printing company has logged 'ink adhesion failure on coated paper' as the top Pareto defect for four consecutive months. Previous corrective action was to slow the press speed. It helped briefly, then the defect returned.

Problem statement: "Ink adhesion failure on coated paper, 3.8–5.2% of monthly output, persisting 4 months. Previous CA (press speed reduction to 80%) produced improvement in months 2 and 3 but failure rate returned to 4.9% in month 4."

Six-M session, 90 minutes:

Man: operators on the afternoon shift (where 71% of failures concentrate per NCR analysis) have different training on press temperature calibration than morning shift. Evidence: training register shows afternoon shift lead trained 14 months ago; morning lead trained 3 months ago when new SOP was issued. Likelihood: High.

Machine: press drum temperature sensors — last calibration 7 months ago, interval is 6 months. Machine parameter log shows afternoon line 2 running 4–6°C lower than specified for this substrate. Evidence: calibration log + parameter log from last 8 weeks. Likelihood: High.

Method: ink viscosity check SOP updated 3 months ago; afternoon shift lead acknowledged update but no re-training documented. Evidence: SOP revision record + training register (no afternoon shift entry post-update). Likelihood: Medium.

Material: coated paper lot changed to a different supplier in month 2. IQC records show the new lot was accepted on visual inspection only — no surface-energy measurement. Evidence: IQC log for months 2–4. Likelihood: Medium.

Measurement: surface energy tester not in the tool list for receiving inspection. No calibration record exists for the one portable instrument in the facility. Likelihood: Low (tool may not be relevant if other causes are confirmed first).

Mother Nature: no evidence of temperature or humidity deviation in the environment log. Likelihood: Low.

CAPA candidates: (1) Machine — recalibrate press drum temperature sensor, set 6-month calendar interval. (2) Man — re-train afternoon shift lead on updated SOP, document with signature. (3) Material — add surface-energy measurement to IQC spec for coated paper. Three CAPAs, each opened before the session ends.

Verification gate: CAPA 1 (temperature sensor recalibration) — check adhesion failure rate on line 2 afternoon shift in the 10 production days following recalibration. QC lead to report at next weekly briefing.

SECTION 6

The Worksheet

Tear this out, copy it onto a fresh sheet, or fill it in directly.

Root-Cause Analysis Fishbone — Chronic Defect

For defects that have appeared in three or more consecutive monthly Pareto reports without permanent resolution. Run as a 90-minute cross-functional session.

CAUSE CATEGORY	POTENTIAL FACTOR	SUPPORTING EVIDENCE (NCR REF OR OBSERVATION)	LIKELIHOOD (HIGH / MEDIUM / LOW)

SECTION 6 (CONTINUED)

Reflection Prompts

After filling in the worksheet on the previous page, work through these.

1. Six rows per cause category (three rows each for Man, Machine, Method, Material, Measurement, Mother Nature). For each potential factor, the evidence column must contain a data reference — an NCR number, a shift record date, a supplier lot, a calibration log entry. 'Team says so' is not evidence. If no data reference exists for a suspected factor, that factor goes to the bottom of the likelihood ranking until data is collected.

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2. After the session: which two or three factors have both High likelihood AND data evidence? Those are the corrective action candidates. Write one CAPA for each. Do not open CAPAs for Medium or Low likelihood factors before High-evidence ones are investigated and closed.

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3. Verification gate before closing the fishbone session: for the top-ranked factor, what data would confirm or disprove it within the next two weeks? Name the data source, the person who will collect it, and the date they will report back. Without this step, the fishbone produces a list, not an investigation.

SECTION 7

Tips and Traps

TIPS

- Send the three-month NCR data brief to participants before the session, not during it. Participants who see the data for the first time in the session spend the session reading, not investigating.
- Separate the 'list all factors' phase from the 'rank likelihood' phase. If ranking happens during listing, the group anchors on the first plausible cause and stops exploring. Complete all six categories before anyone assigns likelihood.
- Assign the verification task to the person with direct access to the relevant data source — not the person who is most available. Access determines speed of verification.
- If the top-ranked factor, once verified, turns out not to be the cause, do not re-run the fishbone from scratch. Go back to the original sheet and elevate the next-ranked factor with data. The investigation continues from existing work.

TRAPS

- Filling the Evidence column with 'team observation' or 'general knowledge.' These entries belong in Low likelihood by definition. Evidence is a document reference with a date — nothing else qualifies for High.
- Opening six CAPAs from one fishbone session. If more than three factors are ranked High with evidence, the scope is too broad. Either the problem statement is too vague (multiple defects combined into one) or the team needs to sequence the CAPAs and close the first before opening the next.
- Treating the fishbone session as the corrective action. The session produces candidates. The CAPA is the corrective action. The verification is what confirms whether the action worked. All three are different steps.
- Skipping the Mother Nature category because it 'seems unlikely.' Temperature and humidity variation is the silent cause in many adhesion, seal, and dimensional defects. It takes two minutes to check the environment log. Check it.

SECTION 8

Appendixes

Appendix A — Problem Statement Template

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Fill this before the session. Post it at the top of the fishbone sheet.

Defect type        : _____________________________________
Frequency (3-month avg) : ______% of ______ units produced
Concentration      : Shift ___ / Line ___ / Material lot ___
Previous corrective actions tried:
  1. _____________________________ (Month: ___)  Result: ___
  2. _____________________________ (Month: ___)  Result: ___
Why previous actions did not hold: _____________________

A completed problem statement above means the session starts
with shared context, not with 30 minutes of background-giving.
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Appendix B — CAPA Opening Card (per candidate factor)

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CAPA Number    : CAPA-YYYY-NNN
Date Opened    : _______________
Linked Fishbone: [defect type] session [date]
Root Cause Identified: _____________________________
Data Evidence  : [NCR ref / log date / shift record ref]
Corrective Action Planned: _________________________
Person Responsible: ________________________________
Target Completion Date: ____________________________
Verification Method: check [metric] on [date] — report to [name]
Date Closed    : _______________  Result: _____________

Open one card per CAPA candidate. File with the fishbone sheet.
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CONFIRMATION

WHERE THIS WORKSHEET COMES FROM

Quality Control Systems

Consistent Quality Is the Result of a System, Not Inspection

by Ibrahim Anwar

This worksheet is one of nine in the *Quality Control Systems* companion worksheet pack. The full pack is grouped into three categories: high-volume worksheets you can run weekly, niche-search worksheets for rare but high-value situations, and specific-case worksheets that walk you through a single concrete scenario.

Every framework, decision filter, and figure used in these worksheets is drawn from the chapters of the source book. The book sets the diagnosis, the worksheets give you the form to act on it.

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