

SPECIFIC-CASE

WORKSHEET 7 OF 9

Defect Rate Jumps 4x in One Week

Scenario: your weekly FPY drops from roughly 95% to below 80% in a single production week. No obvious machine failure, no operator change. The jump is large enough that it cannot be random variation. This worksheet structures the investigation before you spend money or make accusations.



Complementary worksheet for
Quality Control Systems
by Ibrahim Anwar

What This Is For

A 4x defect rate jump in a single week has a specific cause. It is not bad luck and it is not random process variation — statistical process control theory is clear that jumps of this magnitude are special cause events, meaning something changed in the process, the material, the equipment, or the environment. The difficulty is that multiple things usually change in a production week, and the investigation can scatter across all of them unless it is structured.

This worksheet runs the investigation in a fixed sequence that builds from narrow data (which defect type? which shift?) toward broader hypotheses (material lot? environment?) before arriving at a cost estimate that determines whether the corrective action is within the operator's budget authority or needs management escalation.

Benefits

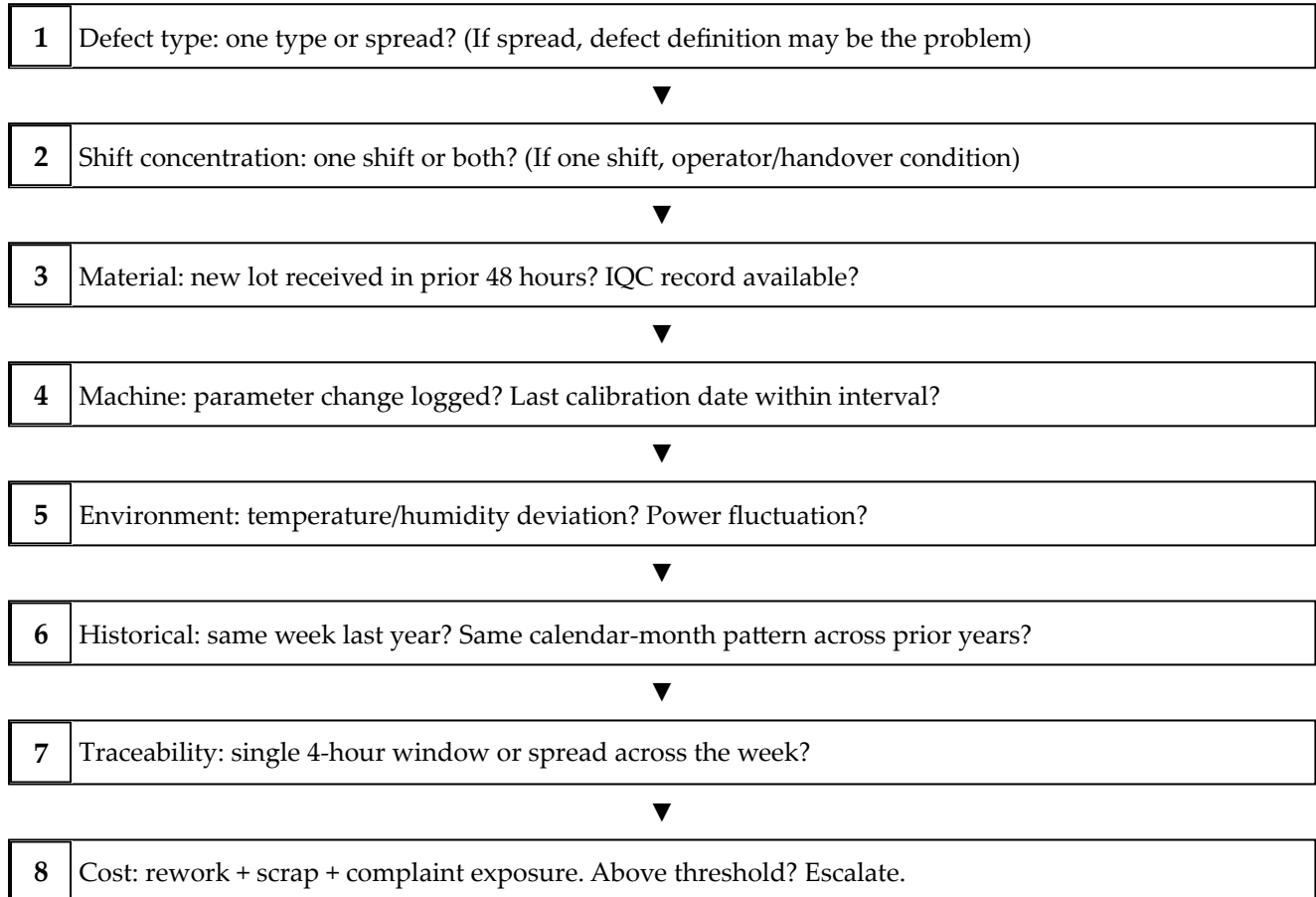
What you get when you actually run this worksheet on a real situation:

- Sequences the investigation to narrow the hypothesis space before opening a CAPA — avoiding the mistake of acting on the first plausible cause rather than the best-evidenced one.
- Row 4 (IQC result for new material lot) is the highest-yield question in most jumps: checking it takes five minutes and closes or opens the largest single category of likely causes.
- Row 10 (cost estimate) converts the event from a quality incident into a financial figure, which determines who needs to authorize the corrective action and how much the fix budget should be.
- The shift-concentration question (row 2) immediately separates process-condition causes (both shifts affected equally) from operator or handover causes (one shift carries the defects).
- The historical search (row 8) identifies whether this is a genuinely new event or a recurring seasonal pattern — two completely different responses.

Framework To Use

— Narrow-Then-Hypothesize

Start with what the data already shows (defect type, shift, timing), then work outward to candidates (material, machine, environment) — in that order, not simultaneously.



How To Use

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

- 1** Run this sheet within 48 hours of noticing the FPY drop — not at week end. The sooner the investigation starts, the more data is still accessible: shift logs, operator rosters, material lot records, and machine parameter logs degrade in specificity as days pass.
- 2** Fill rows 1 and 2 first, from IPQC and defect log data already on hand. Do not start interviewing people until you know which defect type and which shift to ask about.
- 3** Row 3 and 4 require physically pulling the IQC receiving log for the prior week. If the IQC log does not exist or cannot be retrieved, that is row 4's finding — and it is itself a CAPA trigger regardless of whether this lot caused the problem.
- 4** Row 5 requires the machine parameter log or operator setup sheet. If neither exists, the machine is an untested hypothesis that cannot be confirmed or denied.
- 5** Row 8 requires searching NCR records from the same calendar week in prior years. Even two years of data is enough to identify seasonal patterns.
- 6** Row 9 asks whether defective units concentrate in a specific time window. Pull time stamps from IPQC records for the defective units. If 70% concentrate in a 4-hour window, something changed at the start of that window.
- 7** Row 10: multiply defective units by COGS for rework cost, add scrap cost for units beyond salvage, add complaint exposure estimate if any units may have shipped. If total exceeds your management escalation threshold, stop and escalate before selecting a corrective action.

Example Use

A snack manufacturer's weekly FPY falls from 94.3% to 76.1% between Monday and Friday. No operator change. No machine maintenance reported. The shift supervisor raises it Thursday afternoon.

Row 1: Dominant defect type — "underweight" accounts for 83% of all defect events this week per the IPQC tally. Not spread; concentrated in one type. This immediately focuses the investigation on the weighing and portioning stage.

Row 2: Shift concentration — Shift A (morning) accounts for 68% of the week's underweight units despite producing 52% of total volume. Shift B is elevated but not as dramatically. Shift A is the primary focus.

Row 3: Material lot — a new batch of primary ingredient (flour) was received Tuesday morning, replacing a lot that had been in use for three weeks. IQC log checked.

Row 4: IQC result for Tuesday lot — logged as "received, visual OK." No moisture content measurement recorded. The prior lot had a recorded moisture content of 12.4%. Flour moisture content directly affects how the product settles into the pouch during portioning. High moisture = lower weight per unit at the same fill settings.

Row 5: Machine parameter log — portioning machine fill settings not adjusted between lots. No parameter change logged.

Row 6: Operator composition — same Shift A team as prior weeks. Not a factor.

Row 7: Environment — no humidity or temperature deviation recorded in environment log.

Row 8: Historical — NCR records from the same week last year: zero underweight events in that week. Not a seasonal pattern.

Row 9: Defective units concentrate in Tuesday through Thursday production windows — consistent with the new material lot entering the process Tuesday morning.

Row 10: 340 underweight units this week. COGS \$0.09 per unit. Rework cost: $340 \times \$0.09 = \30.60 . All units detected before shipping — no complaint exposure. Total event cost: approximately \$30.60 plus 2 hours of rework labor at \$4/hour = \$38.60. Below management escalation threshold.

CAPA opened: add moisture content measurement to IQC receiving procedure for flour lots. Immediate corrective action: adjust portioning machine fill settings for the current lot based on moisture measurement taken today. Target fill setting provided to Shift A operator with documentation.

Reflection Prompts

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

1. Ten investigation steps to fill: (1) What defect type accounts for most of the increase — one type or spread across many? (2) Which production shift carries most of the bad units? (3) Was there a new material lot received in the 48 hours before the jump? (4) IQC result for that lot — passed, borderline, or no record? (5) Any machine parameter change in the same window — temperature, pressure, speed? (6) Operator composition: same team as prior week, or any substitution? (7) Environmental factor: temperature, humidity spike from weather or HVAC issue? (8) Has this jump pattern occurred before? Search NCR records from same calendar month last year. (9) Can the defective units be traced to a single 4-hour production window? (10) What is the estimated cost of this event: rework + scrap + potential complaint exposure?

2. After filling all 10 rows: the finding with the most data support is the first CAPA candidate. If rows 3 and 4 both flag the new material lot, IQC failure is the working hypothesis. If rows 5 or 7 flag environmental change, process condition is the hypothesis. Do not open a CAPA until one hypothesis has more support than the others.

3. Cost check from row 10: if the estimated event cost exceeds your management escalation threshold, escalate before corrective action is chosen. The investment in the fix must be proportional to the event cost, and management decides that allocation.

Tips and Traps

TIPS

- Start within 48 hours of the FPY drop. Shift logs, machine parameter logs, and material receiving records are all more detailed when fresh. Investigation that starts a week later is already working with degraded data.
- If row 1 shows the defects are spread across four or five unrelated types with no dominant pattern, the problem may be in the defect definition or inspection method itself — not in production. Check whether the inspection criteria or the inspector changed this week before continuing.
- Row 4 (IQC result) is the fastest single question to answer and closes or opens the largest single hypothesis. Pull it first, even before row 2.
- The cost estimate in row 10 is not a formality. It is the number that determines the proportionality of the fix. Spending \$800 on a process redesign for a \$40 event is a management decision, not a QC decision.

TRAPS

- Starting with row 6 (operator composition) because it feels like the most actionable question. Operator changes are easy to investigate and easy to act on. They are also wrong in the majority of cases where material or machine conditions are the actual cause.
- Skipping row 8 (historical search) because it requires searching paper records. A seasonal cause that was already investigated last year is the most expensive type of rework — you re-run the whole investigation for a known problem. The search takes 15 minutes.
- Opening a CAPA before the dominant hypothesis has more data support than the alternatives. Two competing hypotheses both marked 'likely' produce two corrective actions, neither of which is verified, and the same problem returns in the same form.

Appendixes

Appendix A – Management Escalation Threshold Guide

Set your own threshold before an event, not during one.

Suggested starting thresholds by business scale:

Revenue < \$300K/year : escalate above \$150 event cost
Revenue \$300K-\$1M/year : escalate above \$500 event cost
Revenue > \$1M/year : escalate above \$1,500 event cost

"Event cost" = rework + scrap + complaint exposure + staff time.

The threshold determines who authorizes the corrective action budget, not whether the investigation runs. Investigation always runs. The threshold only changes who signs off on the fix.

Review and update the threshold annually.

Appendix B – IQC Missing Record Procedure

If row 4 shows IQC record does not exist for the new lot:

- Step 1 : Flag the lot for hold pending inspection – do not continue using it until the current batch of defective units is traced or cleared.
- Step 2 : Inspect a sample from the current lot now using whatever parameters are in the IQC spec. Record the result.
- Step 3 : Open a CAPA for the IQC receiving gap independently of the defect rate CAPA. These are two problems: the event, and the system failure that allowed it.
- Step 4 : If the current lot inspection fails, quarantine remaining stock. If it passes, note that the correlation with the defect rate is unconfirmed and continue investigating other rows.



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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