

FREE MANUFACTURING INVESTIGATION TEMPLATE

Root Cause Analysis Checklist

Use this 60-point checklist to investigate problems through factual definition, evidence preservation, event sequencing, cause exploration, occurrence and escape analysis, cause verification, horizontal scope, action linkage, review, and lessons learned.

RCA ID / source

Date opened

Process / product

Investigator / reviewer

Internal manufacturing template. Apply current RCA, CAPA, nonconformance, incident, customer, QMS, risk, and sector requirements. ISO 9001:2015 requires evaluation of causes for nonconformity but does not prescribe one specific RCA technique.

1. Problem definition, failed requirement, scope, ownership, and investigation readiness

1

Confirm the investigation record identifies the problem source, such as nonconformance, audit finding, complaint, incident, defect trend, supplier issue, process deviation, or equipment failure.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: A strong root-cause analysis starts with a precise problem statement. Describe what happened and what requirement was not met without embedding...

2

Verify the problem statement describes the observed condition, failed requirement, location or process, date or period, and objective evidence without assuming the cause.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: A strong root-cause analysis starts with a precise problem statement. Describe what happened and what requirement was not met without embedding...

3

Confirm affected product, material, equipment, process, supplier, customer, lot, batch, serial number, line, shift, or site is identified where applicable.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: A strong root-cause analysis starts with a precise problem statement. Describe what happened and what requirement was not met without embedding...

4

Verify the known problem scope and any still-uncertain boundaries are documented before causal analysis begins.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: A strong root-cause analysis starts with a precise problem statement. Describe what happened and what requirement was not met without embedding...

5

Assign an investigation owner and cross-functional team with knowledge of the affected process, product, equipment, quality controls, and relevant data.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: A strong root-cause analysis starts with a precise problem statement. Describe what happened and what requirement was not met without embedding...

6

Record investigation ID, problem source, date opened, process or product, investigator, process owner, quality reviewer, and target completion date.

RCA

FINAL STATUS | Enter

RCA OWNER | Enter

QUALITY APPROVAL | Enter

Execution tip: A strong root-cause analysis starts with a precise problem statement. Describe what happened and what requirement was not met without embedding...

2. Immediate containment context, evidence preservation, and data protection

7

Confirm immediate containment protects affected product, process, customer, employee, equipment, or other relevant stakeholder while the investigation proceeds.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Root-cause analysis should not be distorted by lost evidence. Preserve failed parts, settings, logs, photos, samples, and records before cleanup, repair,...

8

Preserve failed parts, defect samples, equipment condition, process settings, alarms, electronic logs, photos, test results, labels, and other relevant physical or digital evidence.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Root-cause analysis should not be distorted by lost evidence. Preserve failed parts, settings, logs, photos, samples, and records before cleanup, repair,...

9

Verify evidence is identified, dated, traceable, protected from alteration, and linked to the investigation record where needed.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Root-cause analysis should not be distorted by lost evidence. Preserve failed parts, settings, logs, photos, samples, and records before cleanup, repair,...

10

Confirm repairs, resets, adjustments, rework, cleaning, software changes, or other post-event actions are documented so they are not mistaken for pre-event conditions.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Root-cause analysis should not be distorted by lost evidence. Preserve failed parts, settings, logs, photos, samples, and records before cleanup, repair,...

11

Check interviews, observations, system extracts, measurement data, and samples are collected promptly enough to reduce memory loss or evidence degradation.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Root-cause analysis should not be distorted by lost evidence. Preserve failed parts, settings, logs, photos, samples, and records before cleanup, repair,...

12

Document any missing, destroyed, unavailable, or unreliable evidence and explain how the limitation affects confidence in the analysis.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Root-cause analysis should not be distorted by lost evidence. Preserve failed parts, settings, logs, photos, samples, and records before cleanup, repair,...

3. Facts, timeline, sequence of events, process mapping, and change history

13

Create a chronological timeline from the last known-good condition through detection, containment, and relevant actions taken afterward.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Build the factual sequence before asking why. A timeline and process map often reveal the first point at which normal conditions diverged from expected...

14

Verify the timeline distinguishes confirmed facts, estimates, assumptions, and unknowns rather than presenting all information as equally certain.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Build the factual sequence before asking why. A timeline and process map often reveal the first point at which normal conditions diverged from expected...

15

Map the affected process steps, inputs, outputs, controls, decisions, inspections, handoffs, and interfaces relevant to the problem.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Build the factual sequence before asking why. A timeline and process map often reveal the first point at which normal conditions diverged from expected...

16

Review recent changes to product, process, tooling, equipment, software, supplier, material, staffing, shift pattern, maintenance, inspection, or documentation.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Build the factual sequence before asking why. A timeline and process map often reveal the first point at which normal conditions diverged from expected...

17

Compare actual process execution with the approved procedure, control plan, specification, setup, maintenance method, or intended operating condition.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Build the factual sequence before asking why. A timeline and process map often reveal the first point at which normal conditions diverged from expected...

18

Identify the first confirmed point where actual conditions, results, or controls deviated from the expected process.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Build the factual sequence before asking why. A timeline and process map often reveal the first point at which normal conditions diverged from expected...

4. Cause-and-effect exploration, 5 Whys, fishbone categories, and contributing factors

19

Use an investigation method appropriate to the problem, such as 5 Whys, cause-and-effect diagram, fault tree, barrier analysis, process mapping, comparative analysis, or another approved method.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Generate several plausible causes before selecting one. 5 Whys is useful when supported by evidence, but complex problems often need multiple...

20

Consider people, method, machine or equipment, material, measurement, environment, design, software, supplier, management-system, and organizational factors as relevant.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Generate several plausible causes before selecting one. 5 Whys is useful when supported by evidence, but complex problems often need multiple...

21

Identify possible direct causes, contributing factors, enabling conditions, detection or escape causes, and systemic causes rather than stopping at the first plausible explanation.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Generate several plausible causes before selecting one. 5 Whys is useful when supported by evidence, but complex problems often need multiple...

22

Avoid accepting labels such as 'operator error', 'carelessness', 'training issue', or 'equipment failure' without investigating the conditions and controls that allowed the error or failure.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Generate several plausible causes before selecting one. 5 Whys is useful when supported by evidence, but complex problems often need multiple...

23

Use team knowledge and evidence to challenge assumptions, competing explanations, confirmation bias, and conclusions based only on job title or seniority.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Generate several plausible causes before selecting one. 5 Whys is useful when supported by evidence, but complex problems often need multiple...

24

Document the cause hypotheses considered, evidence supporting or contradicting each, and why hypotheses were retained or rejected.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Generate several plausible causes before selecting one. 5 Whys is useful when supported by evidence, but complex problems often need multiple...

5. Direct cause, contributing causes, detection escape, and systemic control failure

25

Identify the direct physical, technical, procedural, or process condition that immediately produced the observed nonconformity or failure where determinable.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Separate why the defect happened from why it was not prevented or detected. Corrective action is stronger when occurrence, escape, and system-level...

26

Identify contributing conditions that increased likelihood or severity, such as workload, maintenance condition, material variation, environment, sequencing, communication, or process instability.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Separate why the defect happened from why it was not prevented or detected. Corrective action is stronger when occurrence, escape, and system-level...

27

Determine why existing preventive controls, standard work, error-proofing, process limits, maintenance, supplier controls, or design controls did not prevent the issue.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Separate why the defect happened from why it was not prevented or detected. Corrective action is stronger when occurrence, escape, and system-level...

28

Determine why inspection, testing, alarms, audits, reviews, monitoring, or other detection controls did not detect the issue before the observed impact or escape.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Separate why the defect happened from why it was not prevented or detected. Corrective action is stronger when occurrence, escape, and system-level...

29

Review whether management-system weaknesses such as poor change control, unclear ownership, weak training, inadequate resources, document control, or risk review contributed.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Separate why the defect happened from why it was not prevented or detected. Corrective action is stronger when occurrence, escape, and system-level...

30

Document occurrence cause, escape or detection cause, contributing factors, and systemic cause separately when the evidence supports multiple causal layers.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Separate why the defect happened from why it was not prevented or detected. Corrective action is stronger when occurrence, escape, and system-level...

6. Cause verification, testing, reproduction, comparison, and evidence strength

31

Confirm each proposed root cause is supported by objective evidence rather than solely by opinion, correlation, timing, or assumption.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: A suspected cause becomes a verified cause only when evidence shows it explains the problem. Where safe and practical, test the hypothesis by...

32

Where safe and practical, reproduce the failure under the suspected causal condition or demonstrate that changing the condition changes the result as predicted.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: A suspected cause becomes a verified cause only when evidence shows it explains the problem. Where safe and practical, test the hypothesis by...

33

Use comparison with known-good product, equipment, shifts, settings, suppliers, locations, or process states to test competing cause hypotheses where helpful.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: A suspected cause becomes a verified cause only when evidence shows it explains the problem. Where safe and practical, test the hypothesis by...

34

Verify measurement data and test methods used to support the cause are themselves reliable, appropriate, and traceable where required.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: A suspected cause becomes a verified cause only when evidence shows it explains the problem. Where safe and practical, test the hypothesis by...

35

Challenge whether the proposed cause explains the full affected scope, timing, defect pattern, recurrence pattern, and available contradictory evidence.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: A suspected cause becomes a verified cause only when evidence shows it explains the problem. Where safe and practical, test the hypothesis by...

36

Record the verification method, evidence reviewed, test result, confidence level, remaining uncertainty, and rationale for accepting the cause.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: A suspected cause becomes a verified cause only when evidence shows it explains the problem. Where safe and practical, test the hypothesis by...

7. Similar-process review, recurrence history, horizontal scope, and risk connection

37

Search previous nonconformances, CAPA, complaints, audit findings, incidents, maintenance records, supplier issues, deviations, and quality trends for similar events.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Once a cause is verified, search for the same weakness elsewhere. A root cause that exists across similar products, equipment, suppliers, or sites may...

38

Review similar products, processes, equipment, tooling, software, suppliers, sites, shifts, or control methods for the same causal condition.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Once a cause is verified, search for the same weakness elsewhere. A root cause that exists across similar products, equipment, suppliers, or sites may...

39

Confirm the analysis determines whether the issue is isolated, recurring, common-cause, special-cause, or potentially systemic based on available evidence.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Once a cause is verified, search for the same weakness elsewhere. A root cause that exists across similar products, equipment, suppliers, or sites may...

40

Review risk assessments, PFMEA or DFMEA, control plans, hazard analyses, process maps, and prior lessons learned to determine whether the cause or failure mode was previously recognized.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Once a cause is verified, search for the same weakness elsewhere. A root cause that exists across similar products, equipment, suppliers, or sites may...

41

If the cause exists elsewhere, expand containment, inspection, risk review, or preventive action to appropriate comparable areas rather than limiting response to the original event.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Once a cause is verified, search for the same weakness elsewhere. A root cause that exists across similar products, equipment, suppliers, or sites may...

42

Document areas reviewed, evidence found, horizontal scope decisions, and justification for locations determined not to require further action.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Once a cause is verified, search for the same weakness elsewhere. A root cause that exists across similar products, equipment, suppliers, or sites may...

8. Corrective-action linkage, cause-to-action alignment, and action adequacy review

43

Confirm proposed corrective actions directly address verified occurrence causes, escape causes, contributing factors, or systemic control weaknesses identified by the analysis.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Every permanent action should trace to a verified cause or control weakness. Avoid actions that only remind people to be careful when the cause is...

44

Verify immediate correction and containment are not being presented as permanent root-cause corrective action.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Every permanent action should trace to a verified cause or control weakness. Avoid actions that only remind people to be careful when the cause is...

45

Prioritize elimination, engineering, process-design, error-proofing, system, maintenance, supplier, or control improvements where these are more effective than reminders alone.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Every permanent action should trace to a verified cause or control weakness. Avoid actions that only remind people to be careful when the cause is...

46

Confirm required changes to procedures, specifications, control plans, inspection methods, training, equipment, software, supplier requirements, or risk controls are identified.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Every permanent action should trace to a verified cause or control weakness. Avoid actions that only remind people to be careful when the cause is...

47

Define measurable effectiveness criteria that would demonstrate the action controlled the verified cause and reduced or prevented recurrence.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Every permanent action should trace to a verified cause or control weakness. Avoid actions that only remind people to be careful when the cause is...

48

Review whether the action could introduce new risks, failure modes, excessive inspection burden, bottlenecks, or unintended effects requiring additional controls.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Every permanent action should trace to a verified cause or control weakness. Avoid actions that only remind people to be careful when the cause is...

9. Investigation quality review, challenge, approvals, and documentation integrity

49

Confirm the investigation record links problem evidence, timeline, process data, cause hypotheses, analysis method, cause verification, and corrective-action rationale.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Before approving the analysis, ask whether an independent reviewer could follow the evidence from problem statement to verified cause without relying...

50

Verify conclusions distinguish facts, assumptions, hypotheses, verified causes, unresolved questions, and limitations in the available evidence.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Before approving the analysis, ask whether an independent reviewer could follow the evidence from problem statement to verified cause without relying...

51

Check the investigation was reviewed by personnel with sufficient technical and process knowledge to challenge weak causal conclusions.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Before approving the analysis, ask whether an independent reviewer could follow the evidence from problem statement to verified cause without relying...

52

Confirm required quality, engineering, EHS, supplier, customer, regulatory, or management approvals are obtained based on the type and significance of the issue.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Before approving the analysis, ask whether an independent reviewer could follow the evidence from problem statement to verified cause without relying...

53

Verify electronic or paper investigation records are attributable, dated, controlled, retrievable, and corrected according to approved record-integrity rules.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Before approving the analysis, ask whether an independent reviewer could follow the evidence from problem statement to verified cause without relying...

54

If the investigation cannot identify a verified cause, document the uncertainty, additional monitoring, interim controls, and rationale for risk-based decisions rather than inventing a cause.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Before approving the analysis, ask whether an independent reviewer could follow the evidence from problem statement to verified cause without relying...

10. Lessons learned, effectiveness handoff, trend analysis, closure, and management sign-off

55

Confirm verified root causes and relevant contributing factors are transferred accurately into the corrective-action or CAPA record without changing the evidence-based conclusion.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Root-cause analysis ends with verified learning, not a diagram. Feed the cause into corrective action, effectiveness review, risk controls, training, audits,...

56

Verify the effectiveness-review plan is linked to the cause and action, with defined criteria, monitoring period, recurrence measures, owner, and review date.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Root-cause analysis ends with verified learning, not a diagram. Feed the cause into corrective action, effectiveness review, risk controls, training, audits,...

57

Trend root-cause categories across investigations to identify recurring equipment, process, supplier, measurement, training, design, change-control, or management-system weaknesses.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Root-cause analysis ends with verified learning, not a diagram. Feed the cause into corrective action, effectiveness review, risk controls, training, audits,...

58

Use lessons learned to update risk assessments, PFMEA or DFMEA, control plans, inspection plans, maintenance, design rules, supplier controls, procedures, or audit focus where appropriate.

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Root-cause analysis ends with verified learning, not a diagram. Feed the cause into corrective action, effectiveness review, risk controls, training, audits,...

59

Escalate repeated root causes, recurring ineffective investigations, overdue analyses, or systemic weaknesses to management review or equivalent leadership oversight where appropriate.

CRITICAL

RCA

RCA item	Current status	Owner	Evidence	Next action
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Execution tip: Root-cause analysis ends with verified learning, not a diagram. Feed the cause into corrective action, effectiveness review, risk controls, training, audits,...

60

Record final RCA status, verified cause, residual uncertainty, corrective-action linkage, horizontal scope, effectiveness-review date, investigator, quality reviewer, process owner, and management approval.

CRITICAL

RCA

FINAL STATUS | Enter

RCA OWNER | Enter

QUALITY APPROVAL | Enter

Execution tip: Root-cause analysis ends with verified learning, not a diagram. Feed the cause into corrective action, effectiveness review, risk controls, training, audits,...