FAILURE MODES, EFFECTS AND CRITICALITY ANALYSIS (FMECA)

Line 3 Cup Filler System: Risk-Ranked Maintenance Strategy

29 failure modes across 10 subsystems, ranked by annualized dollar risk and food-safety consequence, converted into a funded maintenance strategy.

SAMPLE — FICTIONAL DAT

CLIENT	Larkspur Valley Foods, Inc. — Plant 2 (cultured dairy)
SYSTEM	Line 3 cup filler, from product infeed through case-packer infeed, including its CIP and utility interfaces
REPORT NO.	FMECA-2026-007 · Revision 0 · Issued November 20, 2026
DATA BASIS	24 months of CMMS and downtime history (Nov 2024 – Oct 2026), OEM manuals, plant finance FY2026 standards, and team workshops
METHOD	IEC 60812:2018 FMECA, with criticality ranked in annualized dollars and food-safety, personnel-safety, and regulatory overrides
RELATED WORK	RCA-2026-014 (GR-305 gearbox), whose corrective actions are funded separately and excluded from this business case
TEAM	Apex Reliability Engineering (facilitator) · Maintenance Supervisor · Line 3 Lead Mechanic · Controls Technician · Line 3 Production Supervisor · Food Safety & QA Manager · Plant Controller (financial validation)

Demonstration document. Sample report. All company names, people, data, and financial figures are fictional and shown for demonstration only. The structure, methods, and level of detail match Apex Reliability Engineering client deliverables.

Executive Summary

Decision brief for the Plant Manager and Plant Controller. Sections 1–6 contain the supporting detail.

BOTTOM LINE

Line 3's filler carries **$367.1K a year in failure risk**, and ten failure modes account for 70% of it. A targeted package of 23 maintenance tasks and design fixes costs **$49.5K up front and $14.3K a year**. It is expected to cut risk by $194.8K a year and pays back in **3.3 months**. Four failure modes are deliberately left to run to failure because no task pays for itself.

ANNUALIZED RISK TODAY	CLASS A FAILURE MODES	CASH OUTLAY REQUESTED	PAYBACK, EXPECTED CASE	5-YEAR NPV AT 10%
$367.1K	**12**	**$49.5K**	**3.3 mo**	**$635K**
29 failure modes, 10 subsystems	7 raised to A for food safety, safety, or regulatory reasons	Plus $14.3K/yr recurring maintenance budget	Range 2.6–7.5 months	Range $251K–$820K

DECISIONS REQUESTED

1. **Approve $17.5K CAPEX** for four design changes (FM-01, 17, 22, 29) and **$5.7K** in critical spares inventory.
2. **Raise the Line 3 maintenance budget by $14.3K a year** for new condition-based and time-based tasks. The expected return is 14× the added cost.
3. **Endorse run-to-failure** for FM-10, 19, 23, and 26, each with a spare or exchange plan.

WHAT THE ANALYSIS SHOWS

- FINDING The largest single risk, the GR-305 gearbox ($72.0K/yr), is already being fixed under RCA-2026-014. The rest of the line carries $295.1K/yr.
- FINDING Seal-integrity modes (FM-11, 12, 13) cost $40.1K/yr, mostly in held product rather than downtime. Their risk would not show up in a downtime report.
- JUDGMENT 7 modes have modest dollar risk but are treated as Class A because they touch food safety, guarding, or labeling. They are funded regardless of ROI.

FINANCIAL SUMMARY (PRE-TAX)

	CONSERV.	EXPECTED	HIGH
Risk avoided / yr	$93.5K	$194.8K	$243.6K
Net annual benefit	$79.2K	$180.5K	$229.3K
Payback (months)	7.5	3.3	2.6
5-yr NPV at 10%	**$251K**	**$635K**	**$820K**

Break-even: the package pays for itself if tasks deliver just 14% of their rated risk reduction.

CONFIDENCE

MODERATE Failure frequencies come from CMMS records that lack failure coding (RCA-2026-014, LR-6), so minor stops are likely under-recorded. Task effectiveness factors are engineering estimates. The conservative case cuts both, and it still pays back in 7.5 months.

SAMPLE — FICTIONAL D

1 Scope and Method

The analysis covers the whole filler system as the plant constraint sees it: everything whose failure stops Line 3, degrades the product, or puts food safety at risk.

TABLE 1.1 — SYSTEM BOUNDARY AND RESULTS BY SUBSYSTEM

SUBSYSTEM	FAILURE MODES	CLASS A	ANNUAL RISK TODAY	AFTER PACKAGE
Main drive	3	1	$90,899	$78,077
Conveying	4	1	$49,378	$16,020
Product infeed	3	1	$47,308	$15,933
Sealing	4	3	$45,294	$12,286
Dosing	2	1	$32,858	$10,247
Sanitation	2	2	$29,614	$5,189
Cup handling	3	0	$23,934	$13,384
Controls	4	1	$18,214	$6,563
Inspection	2	2	$15,342	$7,417
Utilities	2	0	$14,268	$7,150
Total	**29**	**12**	**$367,109**	**$172,266**

"After package" keeps GR-305 (FM-04) at today's risk, because its fix is credited to RCA-2026-014 and not to this business case.

WHY DOLLARS INSTEAD OF RPN

A risk priority number multiplies three ordinal 1–10 scores, so equal RPNs can hide very different risks, and an RPN cannot be compared with a budget. IEC 60812:2018 allows criticality-matrix methods as well as RPN. Here each mode is ranked by **annualized risk = failures per year × cost per failure**, which puts every mode on the same scale as the money needed to treat it.

HOW CONSEQUENCE IS VALUED

Cost per failure = downtime hours × $2,615/h + parts and labor + product loss. The $2,615/h blended rate assumes 50% of lost volume is recovered on overtime ($610/h) and 50% is lost at contribution margin ($4,620/h), the same basis as RCA-2026-014.

OVERRIDE RULES

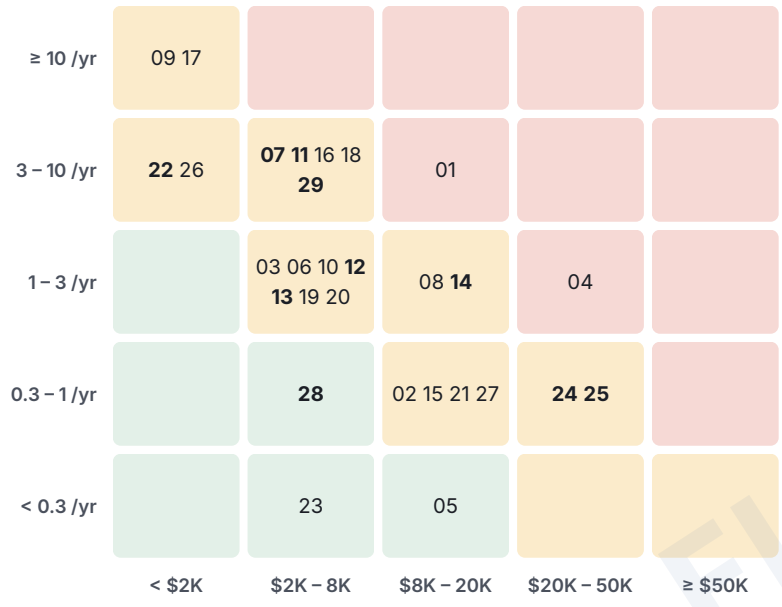
Any mode that can put food safety (F), personnel safety (S), or labeling compliance (R) at risk is Class A whatever its dollar value. Its treatment is justified on risk acceptance, not ROI. Dollar classes: A ≥ $20K/yr, B $5K–20K/yr, C < $5K/yr.

SAMPLE — FICTIONAL D

2 Criticality Results

Risk is concentrated: ten modes carry 70% of the total. The matrix shows where each mode sits; the Pareto ranks them in dollars.

FIGURE 2.1 — CRITICALITY MATRIX (FREQUENCY × COST PER FAILURE)

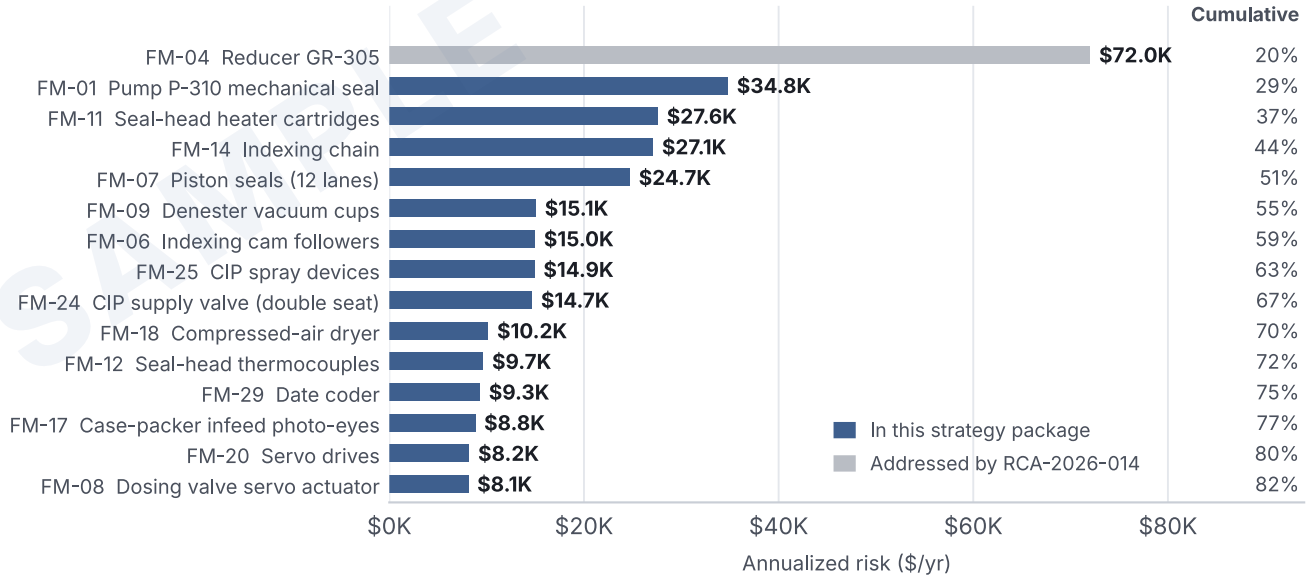


READING THE MATRIX

Rows are failures per year and columns are cost per failure. Shading shows the combined band score: HIGH 7 or more, MEDIUM 5–6, LOW 4 or less. **Bold** IDs carry a food-safety, safety, or regulatory flag.

The matrix is a screening view. Two modes in the same cell can differ in risk by a factor of three, so funding follows the dollar ranking in Figure 2.2. For example, FM-25 and FM-24 sit in a medium cell, but each carries more than $14K/yr in risk.

FIGURE 2.2 — PARETO OF ANNUALIZED RISK, TOP 15 FAILURE MODES



SAMPLE — FICTIONAL DATA

3 FMECA Worksheet

The twelve highest-risk modes in full worksheet form. The remaining 17 are summarized on the next page; the complete worksheet is maintained in the plant CMMS.

ID	ITEM · FAILURE MODE	EFFECT	CAUSE	CURRENT DETECTION	PER YR	$ / FAILURE	$ / YR	CLASS
FM-04	**Reducer GR-305** Bearing seizure from water ingress	Line stop 10–41 h	Washdown ingress (RCA-2026-014)	None	1.8	$39,358	**$72,025**	A
FM-01	**Pump P-310 mechanical seal** Seal leak	Product loss; line stop to replace seal	Dry running after CIP; face wear	Visual	3.0	$11,602	**$34,806**	A
FM-11	**Seal-head heater cartridges** Heater open circuit	Incomplete lid seal; leakers held	Thermal fatigue	Hourly leak check	4.0	$6,902	**$27,608**	A · F
FM-14	**Indexing chain** Elongation / wear	Mis-index; metal wear debris	Wear; lubrication	None	1.5	$18,075	**$27,112**	A · F
FM-07	**Piston seals (12 lanes)** Seal wear	Fill variation; seal fragments in product	Abrasive wear	Checkweigher rejects	8.0	$3,091	**$24,728**	A · F
FM-09	**Denester vacuum cups** Wear / loss of grip	Misfeeds; minor stops	Wear	Minor-stop count	12.0	$1,256	**$15,072**	B
FM-06	**Indexing cam followers** Bearing wear	Mis-index; cup damage	Wear; grease washout	Noise (operator)	2.0	$7,488	**$14,976**	B
FM-25	**CIP spray devices** Blocked / not rotating	Incomplete clean; micro hold	Debris; bearing wear	Visual post-CIP	0.60	$24,890	**$14,934**	A · F
FM-24	**CIP supply valve (double seat)** Leak-by	Cleaning solution in product	Seal wear	None	0.50	$29,360	**$14,680**	A · F
FM-18	**Compressed-air dryer** Wet air (dryer bypassed)	Valve sticking; erratic motion	Dryer fault; drains	None	4.0	$2,542	**$10,168**	B
FM-12	**Seal-head thermocouples** Drift low	Under-temperature seals	Junction degradation	None	2.0	$4,828	**$9,656**	A · F
FM-29	**Date coder** Missing or wrong code	Rework; label non-compliance	Printhead; setup	Manual check	3.0	$3,108	**$9,324**	A · R

Class pills show the final class. A flag letter (F food safety, S personnel safety, R regulatory) marks a mode raised by an override.

SAMPLE — FICTIONAL DATA

3 FMECA Worksheet (continued)

The remaining modes, with the strategy selected for each. Low-risk modes still get a deliberate decision, even when that decision is to run to failure.

ID	ITEM · FAILURE MODE	PER YR	$ / YR	CLASS	SELECTED STRATEGY
FM-02	**Pump P-310 motor bearing** · Bearing failure	0.50	$6,330	B	Monthly vibration route
FM-03	**Balance-tank level transmitter** · Drift / failure	1.5	$6,172	B	Quarterly calibration check
FM-05	**Motor M-305 winding** · Insulation failure	0.20	$3,898	C	Quarterly IR scan + annual PI test
FM-08	**Dosing valve servo actuator** · Actuator failure	1.0	$8,130	B	Stock one actuator; track run hours
FM-10	**Denester air cylinder** · Cylinder failure	1.2	$3,678	C	Run to failure with one spare on hand
FM-13	**Seal pressure regulator** · Pressure drift	1.0	$2,808	A · F	Monthly pressure verification
FM-15	**Chain sprockets** · Tooth wear	0.40	$5,950	B	Inspect with FM-14 check
FM-16	**Discharge belt** · Tracking / belt damage	3.0	$7,476	B	Weekly belt inspection
FM-17	**Case-packer infeed photo-eyes** · Contamination / failure	20.0	$8,840	B	Replace with IP69K sensors
FM-19	**Valve-bank solenoids** · Coil failure	2.0	$4,100	C	Run to failure; spares on hand
FM-20	**Servo drives** · Over-temperature trip	2.5	$8,220	B	Monthly cabinet filter PM + IR scan
FM-21	**PLC I/O card** · Card failure	0.30	$2,924	C	Stock one I/O card
FM-22	**Guard-door interlocks** · Switch failure	6.0	$5,544	A · S	Coded RFID interlocks; annual proof test
FM-23	**HMI panel** · Touchscreen failure	0.20	$1,526	C	Run to failure; vendor exchange
FM-26	**Cup magazine guides** · Wear	6.0	$5,184	B	Run to failure
FM-27	**Lid-feed vacuum pump** · Pump failure	0.50	$5,222	B	Add to vibration route
FM-28	**Checkweigher load cell** · Drift / failure	0.80	$6,018	A · R	Keep daily verification; no change

RUN-TO-FAILURE IS A DECISION, NOT A DEFAULT

FM-10, 19, 23, and 26 have no task cheaper than the failures it would prevent, and none carries a food-safety, safety, or regulatory flag. Each has a spare or vendor exchange in place to keep downtime short. FM-28 keeps its existing daily verification, which already controls its regulatory risk.

SAMPLE · FICTIONAL D

4 Recommended Maintenance Strategy

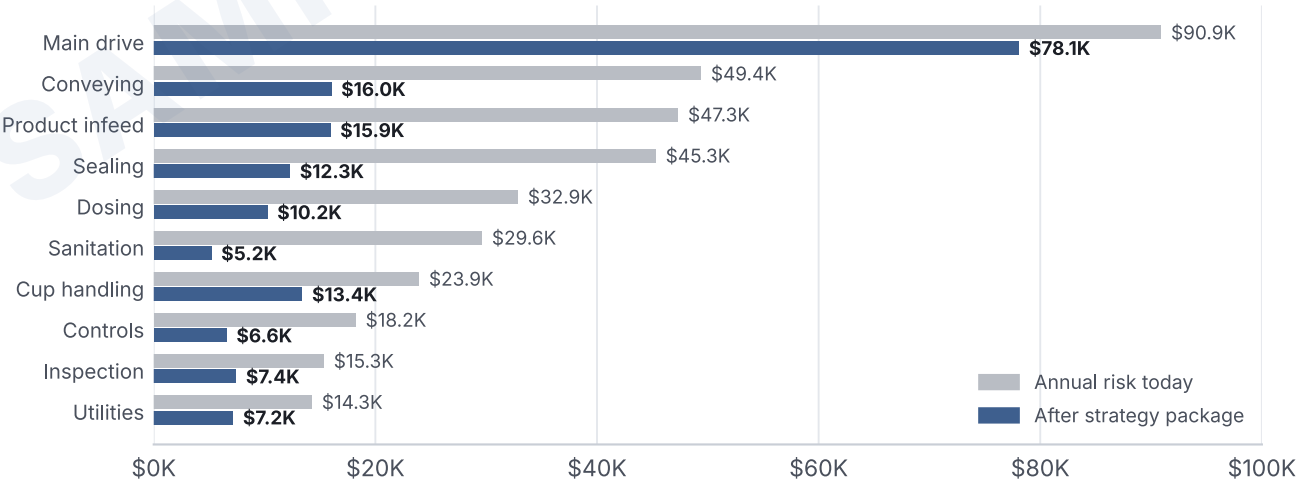
23 tasks grouped by strategy type. Condition-based tasks are chosen where a detectable warning precedes failure, time-based tasks where wear is predictable, and redesign where no task can manage the risk well enough.

TABLE 4.1 — STRATEGY PACKAGE BY TASK TYPE

STRATEGY	FAILURE MODES	TYPICAL TASKS	ONE-TIME	PER YEAR	RISK AVOIDED/YR
Redesign	FM-01, FM-17, FM-22, FM-29	Dry-run interlock, IP69K sensors, coded RFID interlocks, vision code check	$17,500	$0	$42,056
Condition-based	FM-02, FM-05, FM-06, FM-11, FM-14, FM-15, FM-18, FM-25, FM-27	Vibration and ultrasound routes, IR scans, heater-current and dew-point alarms, chain gauging, spray rotation sensors	$12,300	$2,880	$82,183
Time-based	FM-03, FM-07, FM-09, FM-12, FM-13, FM-16, FM-20, FM-24, FM-28	Seal replacements, calibration checks, proof tests, inspections, filter PMs	$0	$10,280	$65,077
Spares	FM-08, FM-21	Servo actuator and PLC I/O card on the shelf	$4,800	$0	$5,527
Run to failure	FM-10, FM-19, FM-23, FM-26	Spare or vendor exchange on hand; no PM	$900	$0	$0
Total			**$35,500**	**$13,160**	**$194,843**

One-time figures exclude 180 h of implementation labor ($14,040), which appears in Section 5. Spares include the FM-10 spare, which supports a run-to-failure decision.

FIGURE 4.1 — ANNUAL RISK BY SUBSYSTEM, BEFORE AND AFTER THE PACKAGE



SAMPLE — FICTIONAL D

Larkspur Valley Foods, Inc. — Plant 2 · Confidential, client internal · Prepared by Apex Reliability Engineering
Sample report. All company names, people, data, and financial figures are fictional and shown for demonstration only.

5 Financial Justification

A $49.5K outlay and $14.3K of added annual OPEX return a positive 5-year NPV in every scenario. Most of the return is avoided lost margin; the maintenance budget goes up while total cost of operation goes down.

TABLE 5.1 — INVESTMENT AND ACCOUNTING TREATMENT

ITEM	CLASS	AMOUNT	ACCOUNTING TREATMENT
Design changes (FM-01, 17, 22, 29)	CAPEX	$17,500	Betterments; capitalization subject to Controller review against the plant threshold
Critical spares (FM-08, 10, 21)	INVENTORY	$5,700	MRO inventory; P&L impact is carrying cost until issued
Monitoring hardware (FM-11, 18, 25)	OPEX	$12,300	Expensed. FM-11 ($6,800) could be capitalized at Controller discretion.
Implementation labor, 180 h	OPEX	$14,040	CMMS task build, routes, procedures, training. Mostly non-incremental; included so cost is not understated.
Total cash outlay (year 0)		**$49,540**	
Recurring task cost (parts, labs, labor)	OPEX/YR	$13,160	New maintenance budget line for Line 3
Spares carrying cost (20%)	OPEX/YR	$1,140	20% of inventory value per year

TABLE 5.2 — SCENARIO ANALYSIS (PRE-TAX, 5-YEAR HORIZON, 10% HURDLE RATE)

	CONSERVATIVE	EXPECTED	HIGH IMPACT
Rated risk reduction (expected frequencies)	$194,843	$194,843	$194,843
Frequency adjustment	-20%	+0%	+25%
Task effectiveness realized	60%	100%	100%
Risk avoided per year	**$93,525**	**$194,843**	**$243,554**
Recurring OPEX added	($14,300)	($14,300)	($14,300)
Net annual benefit	**$79,225**	**$180,543**	**$229,254**
Payback (months, undiscounted)	7.5	3.3	2.6
5-year NPV at 10%	**$250,785**	**$634,860**	**$819,513**
IRR	> 100%	> 100%	> 100%
PV benefit ÷ outlay	6.1×	13.8×	17.5×

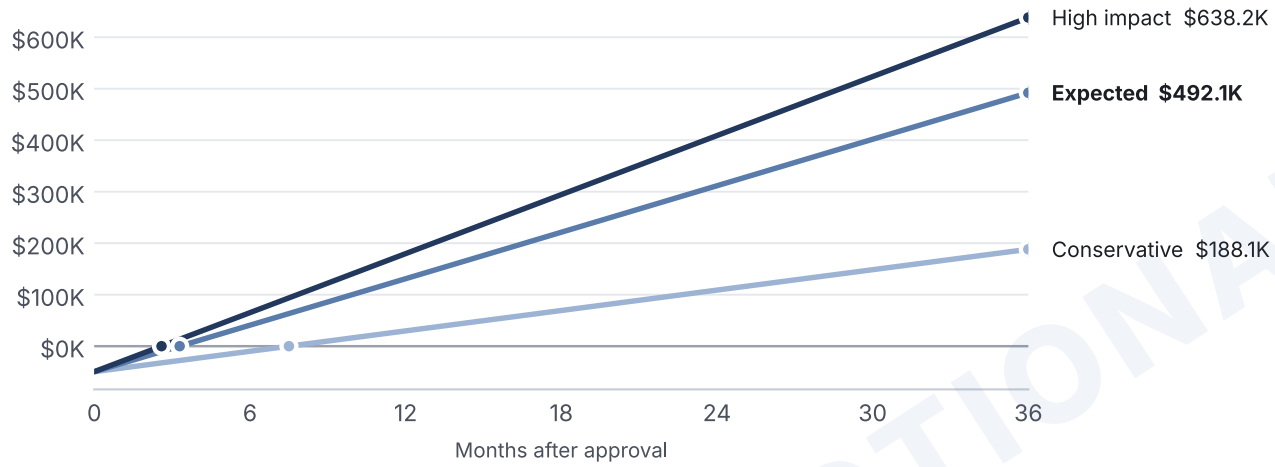
Conservative: Frequencies 20% lower than the CMMS history shows; tasks deliver 60% of their rated risk reduction. **Expected:** Frequencies as in the CMMS history; tasks deliver their rated risk reduction. **High impact:** Frequencies 25% higher (minor stops under-recorded); tasks deliver their rated reduction.

SAMPLE — FICTIONAL D

5 Financial Justification (continued)

The cash curve, the stress tests, and the break-even point all lead to the same conclusion: the case holds under pessimistic assumptions.

FIGURE 5.1 — CUMULATIVE NET CASH POSITION BY SCENARIO (UNDISCOUNTED)



Dots on the zero line mark payback. Line ends show the cumulative position at 36 months.

TABLE 5.3 — STRESS TESTS ON THE CONSERVATIVE CASE

STRESS APPLIED	5-YEAR NPV
Base case (Conservative)	**$250,785**
Downtime cost rate −25%	$190,249
One-time cost +30%	$235,923
Recurring task cost +30%	$234,523
Discount rate 15%	$216,034

The largest sensitivity is the downtime cost rate, because about 68% of avoided cost is downtime.

BREAK-EVEN

NPV reaches zero if the tasks deliver **14% of their rated risk reduction**. The conservative case already assumes 60%.

CONSERVATISM IN THESE FIGURES

Figures are pre-tax and unlevered, with no depreciation tax shield or spares salvage value. They exclude GR-305 (credited to RCA-2026-014) and any quality or customer-confidence benefit beyond recorded product loss.

SAMPLE — FICTIONAL D

6 Implementation and Verification

A 90-day rollout, scheduled into existing sanitation windows so no production time is lost.

TABLE 6.1 — 90-DAY IMPLEMENTATION PLAN

WINDOW	WORK	OWNER
Days 0–30	Load all 23 tasks, routes, and acceptance criteria into the CMMS; order spares and hardware; add failure-mode codes for all 29 modes	Planner · Reliability Engineer
Days 31–60	Install the design changes and monitoring hardware during sanitation windows; first condition-monitoring baselines	Maintenance Supervisor · Controls
Days 61–90	Train crews; QA sign-off on seal-integrity and CIP tasks; first monthly risk review	Reliability Engineer · QA

TABLE 6.2 — VERIFICATION OF EFFECTIVENESS

MEASURE	TARGET	OWNER · CADENCE
Realized annual risk, Line 3 filler	≤ $172.3K/yr by month 12 (from failure-coded work orders)	Reliability · monthly
PM and route compliance	≥ 95% completed on time	Planner · weekly
Seal-integrity holds (FM-11, 12, 13)	≥ 70% fewer held lots than the trailing 12 months	QA · monthly
Minor stops (FM-09, 17)	≥ 60% fewer, measured from line counters	Production · weekly
FMECA review	Re-rank annually, or after any Class A failure	Reliability · annual

TABLE 6.3 — LIMITATIONS AND THEIR EFFECT ON CONCLUSIONS

GAP	EFFECT
CMMS history has no failure coding; frequencies were reconstructed from work-order text and downtime logs	Minor stops are likely under-recorded, so true risk is probably higher. This is covered by the high-impact case.
Task effectiveness factors are engineering estimates INFERENCE	The conservative case assumes 60% effectiveness; break-even is 14%.
Recovery share of 50% assumed for all modes	Mode-level recovery varies. A 25% lower downtime rate still leaves the conservative NPV positive (Table 5.3).

SAMPLE — FICTIONAL D

Sample report. All company names, people, data, and financial figures are fictional and shown for demonstration only.

A Rating Bands, References, and Approval

Scales used in the criticality matrix, the standards applied, and sign-off.

TABLE A.1 — FREQUENCY BANDS

BAND	FAILURES PER YEAR
5	≥ 10 /yr
4	3 – 10 /yr
3	1 – 3 /yr
2	0.3 – 1 /yr
1	< 0.3 /yr

TABLE A.2 — CONSEQUENCE BANDS (COST PER FAILURE)

BAND	COST PER FAILURE
5	≥ $50K
4	$20K – 50K
3	$8K – 20K
2	$2K – 8K
1	< $2K

TABLE A.3 — STANDARDS AND REFERENCES

REFERENCE	TITLE AND USE
IEC 60812:2018	Failure modes and effects analysis (FMEA and FMECA). Analysis method; criticality-matrix approach.
ISO 14224:2016	Petroleum, petrochemical and natural gas industries — Collection and exchange of reliability and maintenance data for equipment. Failure-mode taxonomy adapted for CMMS coding.
21 CFR 117.35, 117.40	Current Good Manufacturing Practice — Sanitary operations; Equipment and utensils. Basis for food-safety (F) overrides.
21 CFR 178.3570	Lubricants with incidental food contact. H1 lubricant requirement in conveying tasks (FM-14).
RCA-2026-014	Root Cause Failure Analysis, GR-305 filler main drive. Source of FM-04 data; consequence valuation basis.

REVIEW AND APPROVAL

Prepared by
Lead Reliability Engineer, Apex Reliability Engineering
Signature _____ Date _____

Food safety review
Food Safety & QA Manager
Signature _____ Date _____

Financials validated by
Plant Controller
Signature _____ Date _____

Approved by
Plant Manager
Signature _____ Date _____

SAMPLE — FICTIONAL D

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