

Process FMEA Matrix

Rev. 01

LN	Function, process	Potential failure modes	Potential effect, impact	Initial risk			
				S	P	D	RPN1
LN	Process	Failure	Impact	S1	P1	D1	RPN1
1 risk	Documenta & records	Uncontrolled documents at point of use	Outdated instructions	7	6	6	252
1 risk	Documenta & records	Not full approval	Deficient review inputs	6	8	4	192
1 risk	Documenta & records	Unclear content	Hard to use, subject to interpretation	8	8	9	576
1 OFI	Documenta & records	Difficult to use	Lost productivity, defects	9	9	9	729
2 rist	Internal audits	Not on schedule	Missed OFI	5	9	2	90
2 rist	Internal audits	Unqualified auditors	Missed OFI	8	9	2	144
2 OFI	Internal audits	Deficient auditor qualification	Missed OFI	8	9	2	144
3 risk	Incoming inspection	Inadequate sampling	Defective parts	9	9	7	567
3 risk	Incoming inspection	Not inspected attributes	Defective parts	9	5	3	135
3 OFI	Incoming inspection	Inaccurate results	Defective parts	7	6	2	84

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LN	Mitigated risk					
	Actions and controls	S2	P2	D2	RPN2	KPIs
LN	Actions and controls	S2	P2	D2	RPN2	KPI
1 risk	Establish a hard copy document distribution matrix	2	3	3	18	No
1 risk	Implement electronic document release system	6	2	2	24	No
1 risk	DCR process requires grammar and spell check. Requirement for validation	2	2	2	8	No
1 OFI	Implement Lean documentation system	2	2	2	8	No
2 rist	Establish and report KPI	3	3	2	18	Yes
2 rist	Conduct internal audotr training	3	3	2	18	No
2 OFI	Outsourced internal audor services	2	2	2	8	No
3 risk	Implement AQL requirements for inspection	5	2	2	20	No
3 risk	Revise and update inspection specification sheets	5	3	2	30	Yes
3 OFI	Visual inspection system	4	3	1	12	No