FAD-FMEA

Functional Analysis Diagrams- assisted FMEA processes

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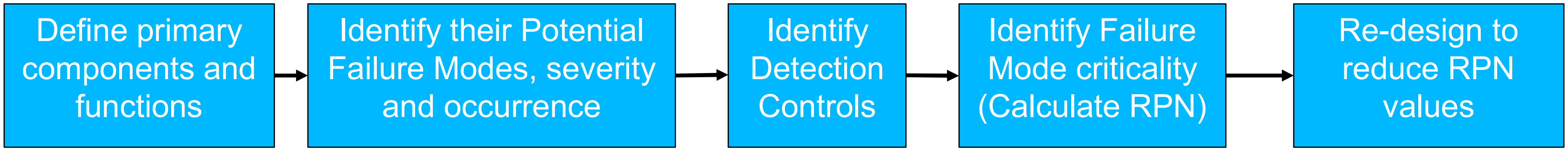
What is FMEA?

Failure Mode and Effects Analysis (FMEA) is a systematic, cross-disciplinary process, aiming to identify and address any potential failure modes (ways in which the product or process can fail to deliver its intended functions) within a product design or process

Based on the *Systems' Engineering* approach, FMEA involves the *Functional Decomposition* of a product or process in order to identify the ways in which a system can fail and evaluate the criticality of these failures. FMEA can be conducted at high level (e.g., the product) or lower levels (e.g., a sub-system). The FMEA process steps are as follows:



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Why conducting FMEA?

- Initially developed for the Defence and Aerospace industries in the 1950s, FMEA processes are nowadays included in standard quality processes such as the Advanced Product Quality Planning (APQP) and the Production Part Approval Process (PPAP)

- FMEA can be conducted independently or as part of APQP/PPAP during product/process design or redesign processes

- FMEA processes can reduce the Time to Market and improve product quality when conducted early in the design process

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Who is involved with FMEA?

FMEA processes require the input of all actors involved with the product. An example of these actors can be:

- Market Research or Customer representative
- Quality Assurance
- Design Engineering (Mechanical/ Electrical/ Software)
- Production Engineering
- Service/ maintenance
- Logistics

The FMEA team should be diverse enough and include all product stakeholders, while small enough to minimise disruption.

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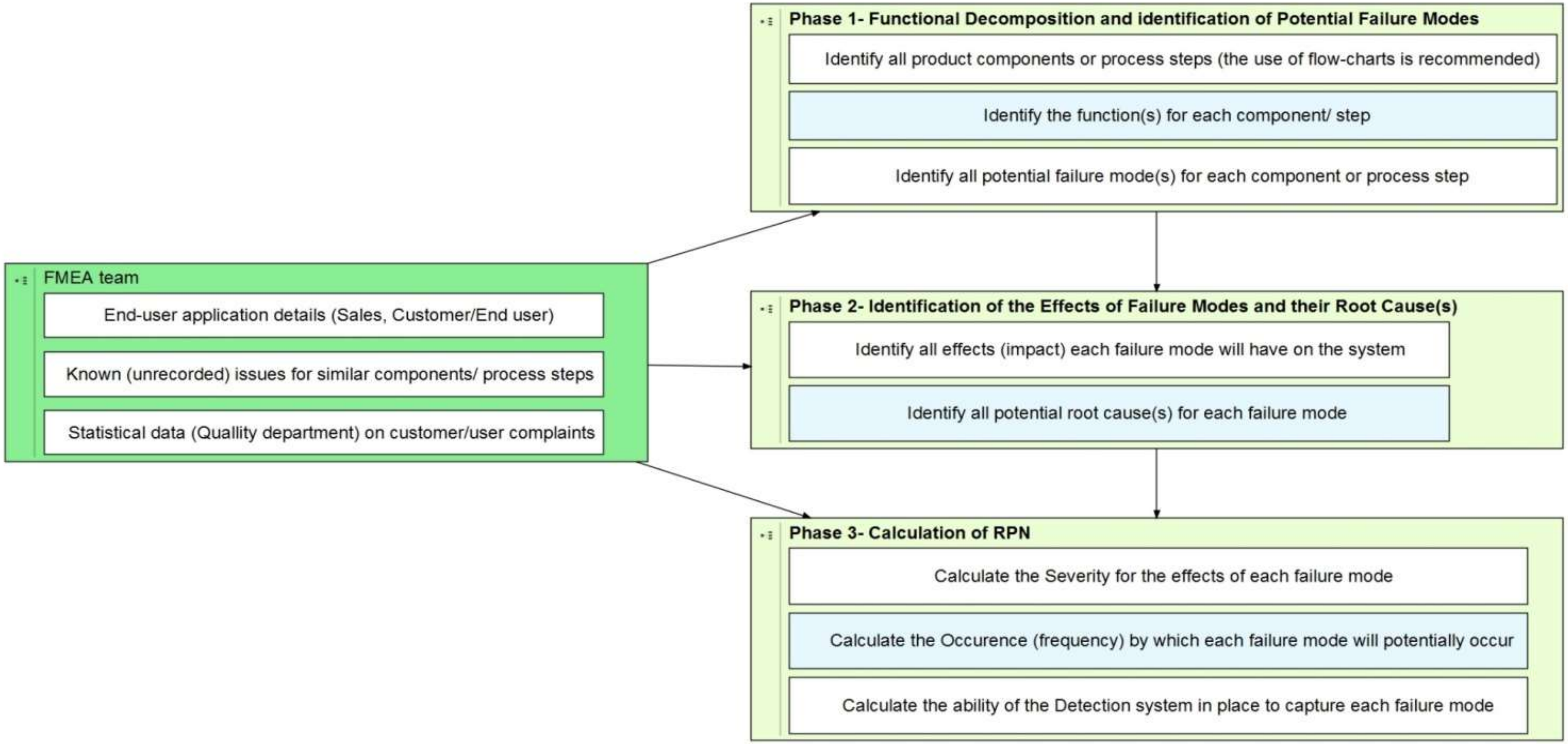
FMEA: How is it done?



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FMEA: How is it normally done?

Component/ Process Step	Function/ Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Current Design				RPN	Recommended Action
						Controls Prevention	Occurence	Controls Detection	Detection		
O-ring housing (piston)	provides sealing faces	leak	oil out of the spring and force loss	8	surface finish, debris	design, manufacturing and inspection processes	3	surface finish testing/ visual	4	96	Review surface inspection procedure
	controls squeeze	leak	oil out of the spring and force loss	8	dimensions, concentricity		2	dim. Inspection	2	32	No action required
	allows safe assembly	leak	oil out of the spring and force loss	8	burrs, sharp edges		3	visual	2	48	No action required
O-ring groove (rod)	provides sealing faces	leak	oil out of the spring and force loss	8	surface finish, debris		2	surface finish testing/ visual	2	32	No action required
	controls squeeze	leak	oil out of the spring and force loss	8	dimensions, concentricity		2	dim. Inspection	2	32	No action required
O-ring	seals	leak	oil out of the spring and force loss	8	seal out of spec or defective		1	visual	8	64	No action required
spool stem	provides sealing faces	leak	oil out of the spring and force loss	8	suface finish		3	surface finish testing	2	48	No action required
	controls squeeze	leak	oil out of the spring and force loss	8	dimensions, concentricity		3	dim. Inspection	2	48	No action required

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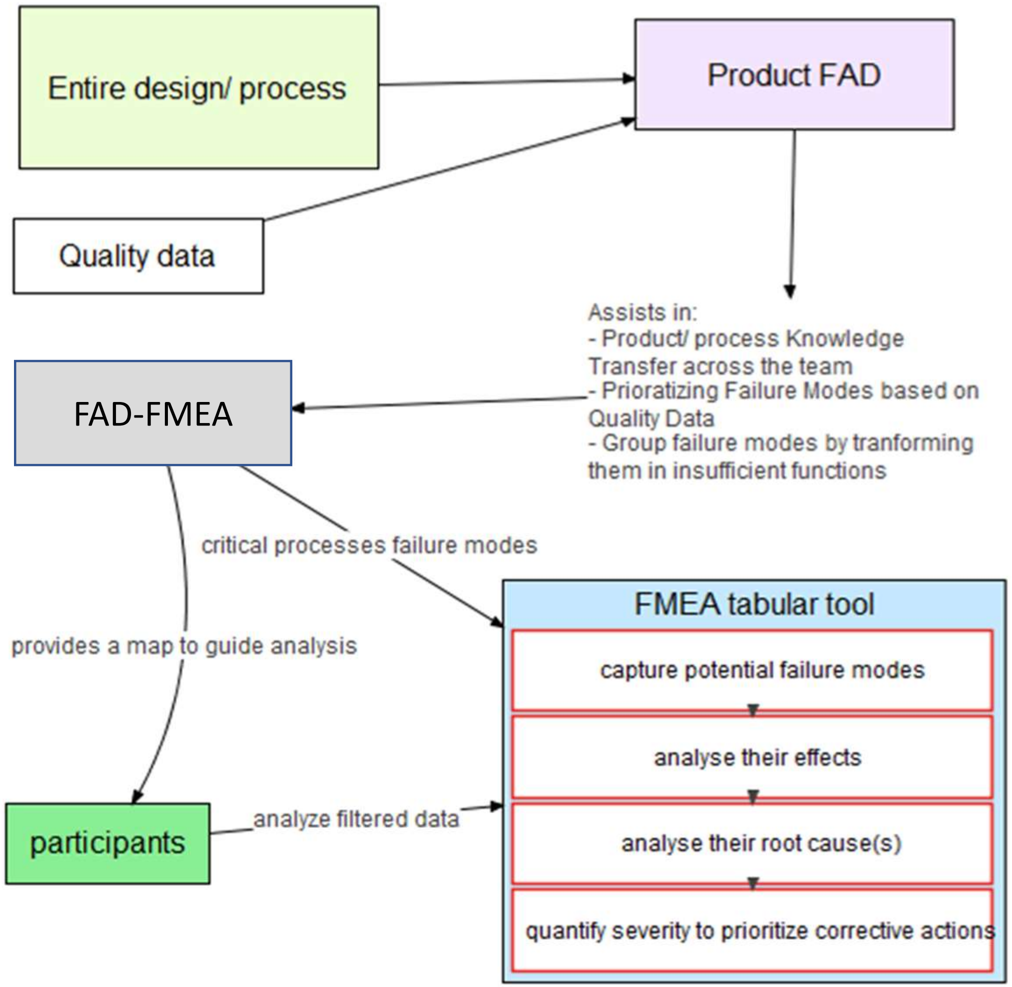
What is FAD-FMEA?



FAD-FMEA was developed to optimise the recourse-efficiency of the FMEA process, and in particular, its initial phase

The FAD-FMEA process involves the development of FAD models of the system in liaison with the FMEA team, before the FMEA sessions

The FAD models provide an intuitive communication platform, assisting the team members to contribute

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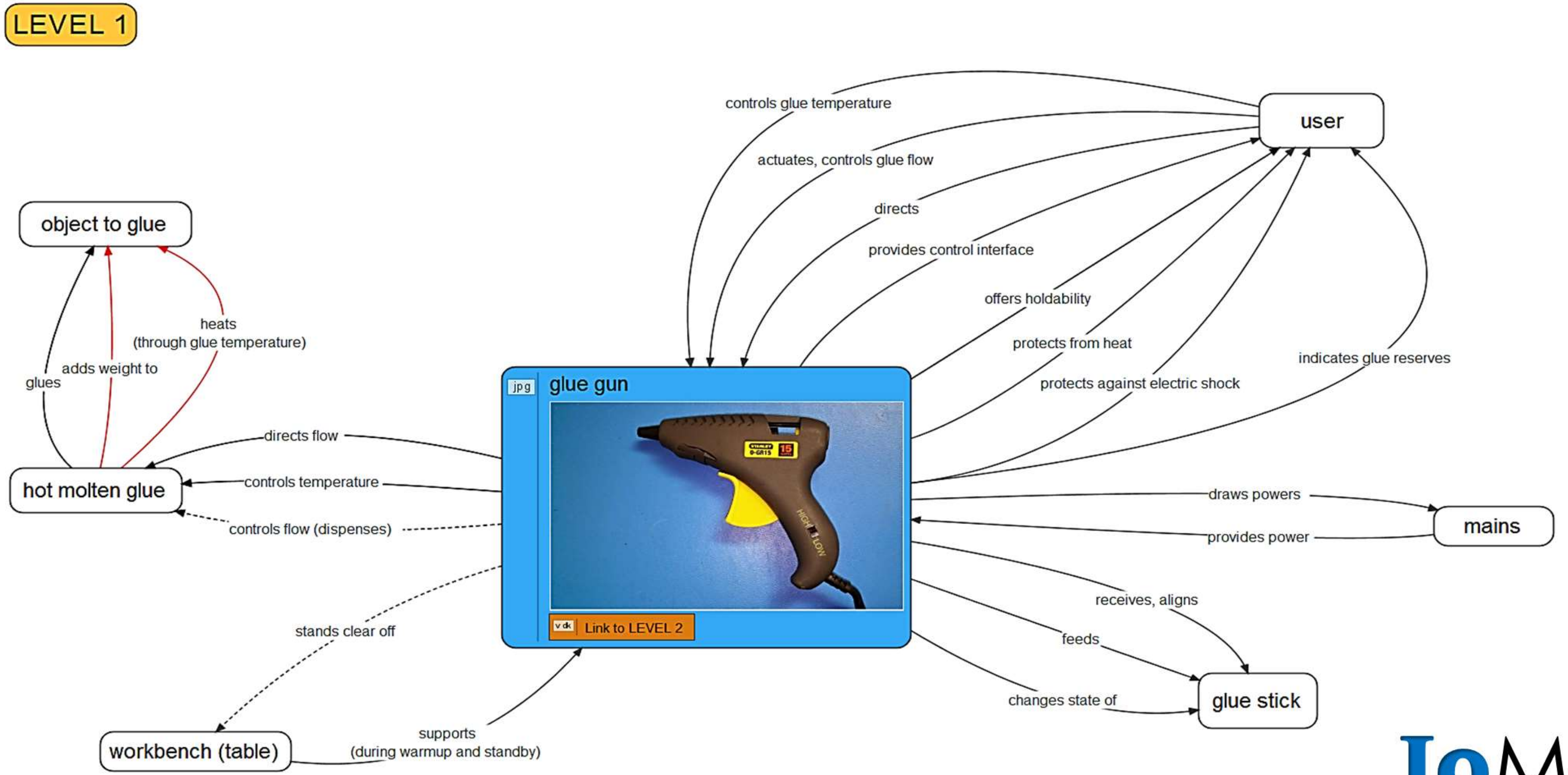
FAD-FMEA process example: Glue gun

Develop a FAD model of the product at “Level 1”, showing its functional interactions with its environment



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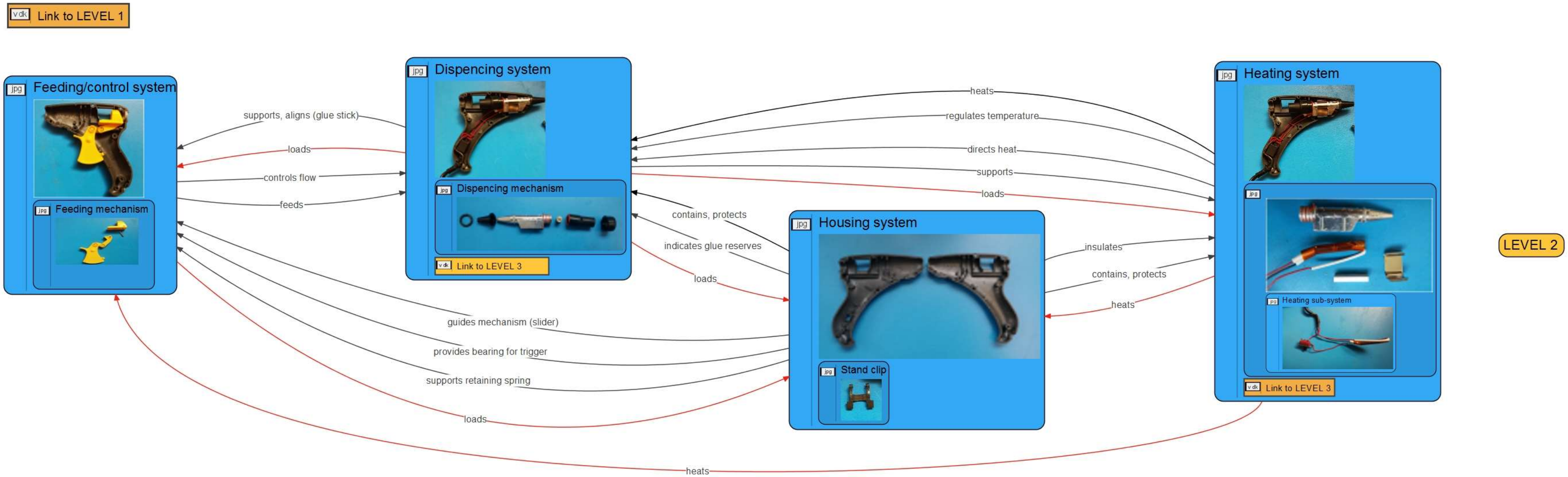
FAD-FMEA process example : Glue gun

Develop a FAD model of the product at “Level 2”, showing the primary sub-systems and their functional interactions



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FAD-FMEA process example : Glue gun

Use the FAD models to populate the FMEA sheet at sub-system level with potential failure modes, effects and severity. Market Research/ customer representatives should be present at this stage.

Component/sub-system	Function/ Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Severity
Dispensing sub-system	control hot glue flow	excessive glue flow	damage object to glue	8
		Low glue flow	prolong process	4
	direct hot glue	miss glue target	damage object to glue	8
Heating sub-system	melts glue (changes state)	glue is solid- no flow	cannot glue object	7
	regulates hot glue temperature	glue is not hot enough	weak bonding	7
			overload/damage feed system	6
		glue is too hot	damage object to glue	8
Housing sub-system	houses/ protects components	Insecure components	limited service life	6
	insulates heat	heat is transferred to user's hands	minor health hazard	8
	insulates mains	fails to insulate mains	major health hazard	10
Feed/control sub-system	interfaces with user	no response on user's input	weak bonding	7
	displace glue stick	fails to displace glue stick	cannot glue object	7

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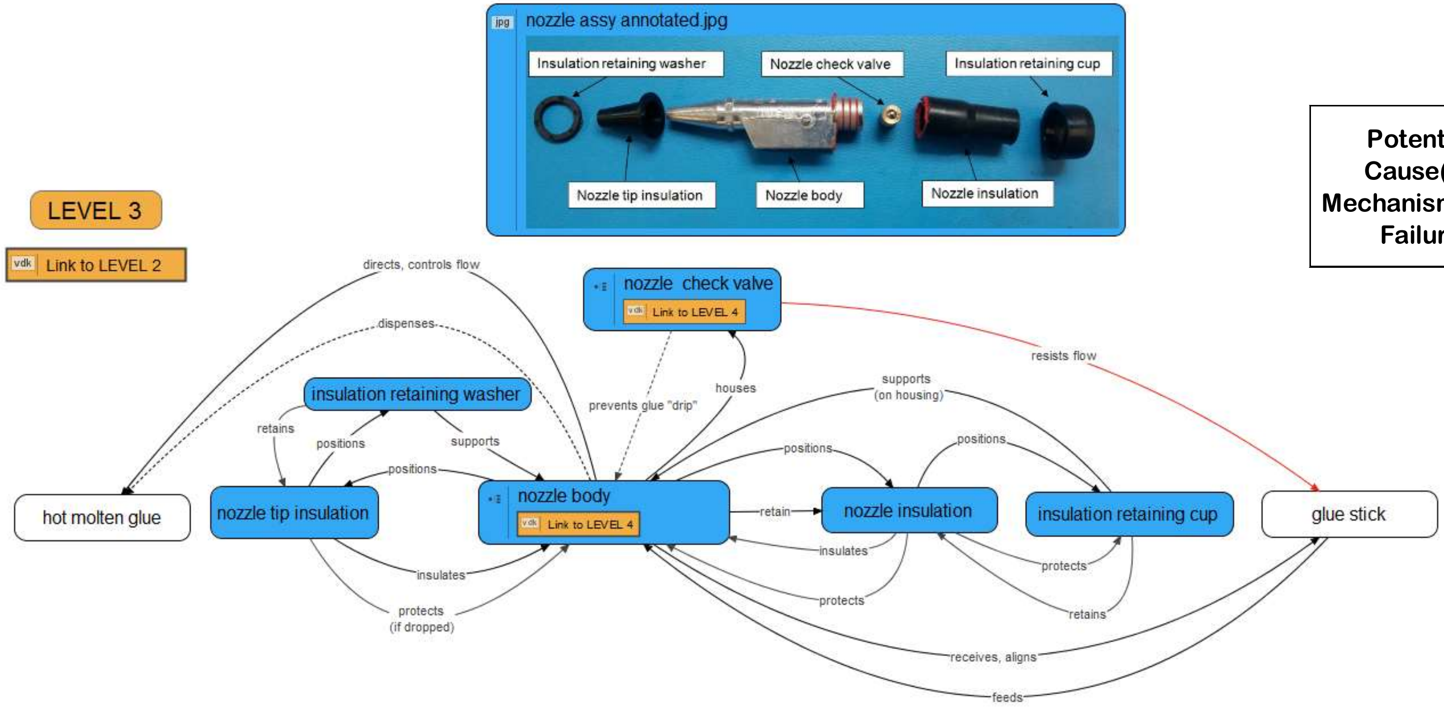
FAD-FMEA process example : Glue gun

Populate the potential causes, occurrence, prevention/detection controls and detection to calculate the Risk Priority Number (RPN) for each failure mode.

Quality Assurance and Engineering representatives should be present at this stage.

FAD models at lower levels can greatly assist identifying potential causes as well as determining the recommended actions



Potential Cause(s)/ Mechanism(s) of Failure	Occurrence	Current Controls - Prevention	Current Controls - Detection	Detection	RPN

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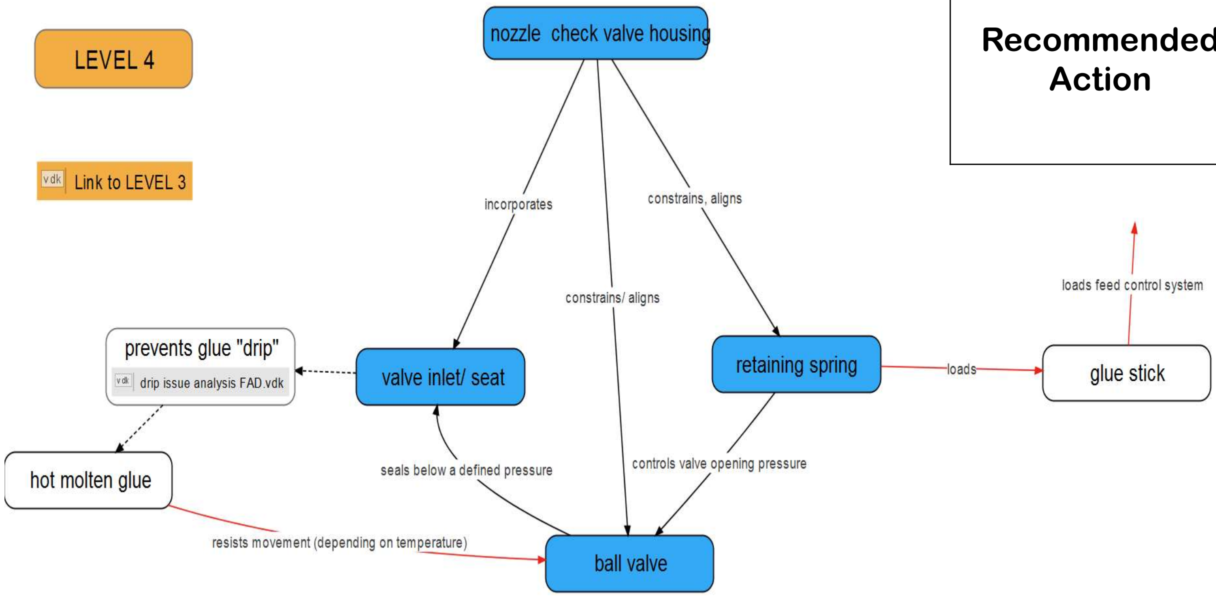
FAD-FMEA process example : Glue gun

The recommended actions, completion date and responsivity are populated for failure modes with high RPN values*. The RPN values are re-calculated after the actions are complete. Functional models at lower levels can significantly assist with the investigation and re-design



		Action Results				
Recommended Action	**Responsibility and Target Completion Date**	**Action Taken**	**Severity**	**Occurrence**	**Detection**	**RPN**

* There is no universally accepted threshold for RPN. However, values above 100 or the highest three are normally actioned

Resources

Severity Rating Scale

Rating	Description	Definition (Severity of Effect)
10	Dangerously high	Failure could injure the customer or an employee.
9	Extremely high	Failure would create noncompliance with federal regulations.
8	Very high	Failure renders the unit inoperable or unfit for use.
7	High	Failure causes a high degree of customer dissatisfaction.
6	Moderate	Failure results in a subsystem or partial malfunction of the product.
5	Low	Failure creates enough of a performance loss to cause the customer to complain.
4	Very Low	Failure can be overcome with modifications to the customer's process or product, but there is minor performance loss.
3	Minor	Failure would create a minor nuisance to the customer, but the customer can overcome it without performance loss.
2	Very Minor	Failure may not be readily apparent to the customer, but would have minor effects on the customer's process or product.
1	None	Failure would not be noticeable to the customer and would not affect the customer's process or product.

Occurrence Rating Scale

Rating	Description	Potential Failure Rate
10	Very High: Failure is almost inevitable.	More than one occurrence per day or a probability of more than three occurrences in 10 events ($C_{pk} < 0.33$).
9	High: Failures occur almost as often as not.	One occurrence every three to four days or a probability of three occurrences in 10 events (Cpk ≈ 0.33).
8	High: Repeated failures.	One occurrence per week or a probability of 5 occurrences in 100 events ($C_{pk} \approx 0.67$).
7	High: Failures occur often.	One occurrence every month or one occurrence in 100 events ($C_{pk} \approx 0.83$).
6	Moderately High: Frequent failures.	One occurrence every three months or three occurrences in 1,000 events ($C_{pk} \approx 1.00$).
5	Moderate: Occasional failures.	One occurrence every six months to one year or five occurrences in 10,000 events ($C_{pk} \approx 1.17$).
4	Moderately Low: Infrequent failures.	One occurrence per year or six occurrences in 100,000 events ($C_{pk} \approx 1.33$).
3	Low: Relatively few failures.	One occurrence every one to three years or six occurrences in ten million events ($C_{pk} \approx 1.67$).
2	Low: Failures are few and far between.	One occurrence every three to five years or 2 occurrences in one billion events ($C_{pk} \approx 2.00$).
1	Remote: Failure is unlikely.	One occurrence in greater than five years or less than two occurrences in one billion events ($C_{pk} > 2.00$).

Detection Rating Scale

Rating	Description	Definition
10	Absolute Uncertainty	The product is not inspected or the defect caused by failure is not detectable.
9	Very Remote	Product is sampled, inspected, and released based on Acceptable Quality Level (AQL) sampling plans.
8	Remote	Product is accepted based on no defectives in a sample.
7	Very Low	Product is 100% manually inspected in the process.
6	Low	Product is 100% manually inspected using go/no-go or other mistake-proofing gages.
5	Moderate	Some Statistical Process Control (SPC) is used in process and product is final inspected off-line.
4	Moderately High	SPC is used and there is immediate reaction to out-of-control conditions.
3	High	An effective SPC program is in place with process capabilities (C_{pk}) greater than 1.33.
2	Very High	All product is 100% automatically inspected.
1	Almost Certain	The defect is obvious or there is 100% automatic inspection with regular calibration and preventive maintenance of the inspection equipment.

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Resources

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