

Potential Failure Modes and Effects
Analysis (Information Sheet)

PFMEA 编号 (PFMEA Number) : 20103680 -PFMEA Rev.C

制程名称 (Process Name) : 反应注塑 Reaction Injection Molding

制程任务 (Process Responsibility) : 成品加工 Finished Good Processing

准备人 (Prepared By) : Chu Libo

适用的产品 (Affected Product(s)) : 20103680 REV C

PFMEA开始日期 (PFMEA Origination Date) : 2024.05.31

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Process / Product Failure Modes and Effects Analysis (PFMEA)																	
产品名料号称/版号： Part Number/Revision：		20103680 REV C	制程任务 Process Responsibility	成品加工 Finished Good Processing	组员 Team Member:	Chew Ee Hang Chu Guochun Zhao Renyan	Lu Chuanhai Feng Yuying Chu Libo	Chen Hang Gan Cheng Wu Zhouwei	PFMEA 日期（开始/版本） PFMEA Date (Begin/Rev)		2024.05.31	文件号/版本号 Document Number/ Revision:	PFMEA-20103680-01				
制程名称 Process Name：		成品加工 Finished Good Processing	准备人： Prepared By：	Chu Li Bo		PFMEA修改日期 PFMEA Revision Date:		/	版本号 Revision:	01							
步骤 Step No.	制程工位 Process Step	主要的制程输入 Key Process Input	潜在失效模式 Potential Failure Mode	潜在失效结果 Potential Failure Effects	S E V 严重性	潜在的原因 Potential Causes	O 发 生 性	目前控制方法 Current Controls	D 检 出 性	R P N 得分	推荐的对策 Actions Recommended	负责人 Resp.	被采取的对策 Actions Taken	S E V 严重性	O 发 生 性	D 检 出 性	R P N
过程步骤 Process steps	当前是哪个制程工位？ What is the process step	当前工位的主要输入是什么？ What is the Key Process Input?	主要的输入会以哪种形式出错？ In what ways can the Key Input go wrong?	对输出变量造成什么影响？输出是只客户要求或者内部要求 What is the impact on the Key Output Variables (Customer Requirements) or internal requirements)？	对客户使用有多严重的影响？ How Severe is the effect to the customer?	什么使输入产生了错误？ What causes the Key Input to go wrong?	失效发生的频率？ How often does cause or FM occur?	目前有什么使用中的控制方法和预防方法？ 需要包含SOP编号 What are the existing controls and procedures (inspection and test) that prevent eith the cause or the Failure Mode? Should include an SOP number.	怎么检出失效？ How well can you detect cause or FM?		针对降低发生率和提高检出性采取什么措施？ What are the actions for reducing the occurrence of the Cause, or improving detection?	谁是对策的负责人？ Whose Responsible for the recommended action?	哪些对策被彻底执行了？ 使用周，月的数据比较 What are the completed actions taken with the recalculated RPN? Be sure to include completion week/month				
10	业务 business	接受定单 Receive Customer Order	订单信息不清楚 Order information unclear	影响生产和出货 Affect production and delivery	4	英文未及时翻译 Translation not done in time	2	由专人接受客户订单，对订单内容进行翻译。将重要信息邮件通知各负责人。 The designated personnel to accept customer's order, translate the contents of the order and email the important information to all person in charge	4	32							
20	生管 Production management	下达生产指令 Issue production order	生产指令不清晰，内容不完整 production order is not clear and the content is not complete	影响生产和出货 Affect production and delivery	4	订单内容识别误差 Order content identification error	2	核对要货订单及BOM表 Verify with PO and BOM list	4	32							
30	采购 procurement	采购配件 Purchase components	配件采购错误 Erroneous of components purchase	影响生产和出货 Affect production and delivery	5	人员失误 Human error	2	核对要货订单及BOM表 Verify with PO and BOM list	3	30							
40	仓库 warehouse	接受配件 Receive components	产品数量及发错货 Quantity is incorrect or wrong parts sent	影响生产和出货 Affect production and delivery	5	人员失误 Human error	2	核对要货订单及BOM表 Verify with PO and BOM list	3	30							
50	IQC	进料检验 Incoming Quality Inspection	漏检 Missing Incoming material Inspection	影响生产和出货进度 Affect production and delivery schedule	4	来料检验流程错误 Error in IQC	2	来料检验报告和供应商提供的质保书 IQC inspect report& COC From suppliers	5	40							
			检验结论错误 Erroneous inspection result	影响生产和出货进度 Affect production and delivery schedule	6	来料检验错误 Error in IQC	2	来料检验报告和供应商提供的质保书 IQC inspect report& COC(Certificate) From suppliers	3	36							
60	仓库 warehouse	配件储存 Store components	包装损坏 Package was destroyed	原材料受污染、受潮 Raw material easy to be contaminated and affected by damp conditions	3	在包装过程中外力太大造成 External force during packing	3	6S检查 6S checking	4	36							
			物料损坏 Raw material damaged	影响生产和出货进度 Affect production and delivery schedule	5	在包装过程中外力太大造成 External force during packing	2	6S检查 6S checking	4	40							
			数量错误 Wrong quantity	影响生产 Affect production	4	库存管理过程中出问题 Mistake in inventory control	3	库存管理台账，定期盘点 Inventory management ledger，Cycle count	3	36							
70	生产部 production department	领料 Material Requisition	使用错误的料号，和错误的数量，没有按照先进先出的原则 Use of wrong part number and/or quantity; not following FIFO	产品返工或报废，产品质量问题无法追溯 Rework or scrap,hard to trace for quality issues	6	外包装无日期，品名等标识，仓管员未按照先进先出执行 Packaging lacks labels for date, part number, etc.; warehousing staff did not comply with FIFO	2	仓库管理员收货并对产品的标识及数量等进行核对，材料标识清晰，先后批次标识区分摆放。 Warehouse verify the quantity and identification card of material,Clear labelling, organise labelled materials according to FIFO	4	48							
80	生产部 production department	CNC加工 CNC machining	尺寸超差 Dimensions out of tolerance 关键尺寸参见检验计划 Refer to plan for dimesions	产品返工或报废 Rework or scrap	5	1. CNC条件不佳 2. CNC conditions not optimised 2.未按照指导书要求作业 2. Failure to follow instructions	2	CNC程序单 CNC Parameters Card	5	50							
90	生产部 production department	外协本色铬酸盐处理 Outsource for surface treatment	运输过程碰伤不良。 Damage during transportation.	产品返工或报废 Rework or scrap	5	包装方法不当造成 The packaging method is unreasonable	2	包装规范 SOP Packaging	2	20							
100	喷漆 painting	喷涂 Painting	产品喷漆不良。 Finishing issue on painted surface.	导致产品返工，追溯困难 Parts need to rework, hard to trace	6	未按照指导书要求作业 Failure to follow instructions	2	喷漆件检验作业指导书 Spray paint inspection work instruction	2	24							
		喷漆品全检 Complete inspection of painted products	产品表面碰划伤 Scratches on part surface	产品返工或报废 Rework or Scrap	6	人员及检验员疏忽 Staff negligence	1	检验员100%检查 100% full inspection	2	12							
		油漆调配 Paint Mixing	油漆调配比例不对 Wrong paint mixing ratio	喷漆后的产品油漆层耐磨测试达不到要求。 The paint layer abrasion resistance test of the part after painting failed to meet the requirements.	7	人员及检验员疏忽 Staff negligence	1	按照油漆厂家配方进行调配，将配比写入喷漆作业指导书内，每批油漆调配时，做好相关调配记录。 Make the mixture according to the paint manufacturer's formula, record the ratio into the spray painting operation instructions. When mixing each batch of paint, make relevant mixing records.	6	42							
			油漆，固化剂，稀释剂用错。 Wrong paint, hardener and thinner were used.	1.附着力达不到标准要求，喷漆后产品表面会橘皮纹。 2.油漆无法固化。 3.造成喷漆完成后，产品外观面感与标准色板差距较大，颜色不符合要求。 1. The adhesion does not meet the standard requirements, the surface of the part will have orange peel patterns after spray painting. 2. The paint cannot be cured. 3. After the painting is completed, the appearance and feel of the part are quite different from the standard color plate, the color does not meet the requirements.	6	作业人员不清楚油漆配方。 The operator not sure of the paint formula.	1	将油漆，稀释剂，固化剂型号和配比，写入喷漆作业指导书。每批调配严格按指导书要求调配。 Record the paint, thinner, curing agent models and ratios into the spray painting operation instructions. Each batch is prepared in strict accordance with the instructions.	3	18							

		喷漆过程 Spray painting process	喷漆过程中，灰尘落到产品表面，造成产品颗粒不良。 During the painting process, dust falls on the surface of the part, causing defective part particles.	产品返工 Rework	5	产品打磨后表面有灰尘未清理干净，带入到喷漆室 After the part was polished, the dust on the surface was not cleaned and brought into the spray paint room.	3	1.要求作业员每天上下班打扫现场卫生。 2.产品完成抛光打磨后，将表面灰尘清理干净再流入喷漆室。 1. Operators are required to clean the site every day on and off work. 2. After the part is grinded and polished, clean the surface dust before flowing into the spray paint room	3	45							
			油漆喷涂后烘烤温度偏低 The heating temperature is too low after paint spraying	造成油漆干不透，附着力差。 As a result, the paint cannot dry completely and has poor adhesion.	6	烘烤温度设置不当 Improper heating temperature setting	2	确定好烘烤温度，加入到喷漆作业指导书。员工按指导书要求作业。 Determine the heating temperature and add it to the spray painting instructions. Employees work according to instructions.	3	36							
110	FQC	喷漆品全检 Complete inspection of painted products	产品表面碰划伤 Scratches on part surface	产品返工或报废 Rework or Scrap	6	人员及检验员疏忽 Staff negligence	1	检验员100%检查 100% full inspection	2	12							
120	FQC	产品在货架上摆放整齐，避免碰撞 The products are neatly placed on the shelves to avoid collisions.	产品表面碰划伤 Scratches on part surface	导致产品返工，追溯困难 Parts need to rework, hard to trace	6	人员及检验员疏忽 Staff negligence	1	检验员100%检查 100% full inspection	2	12							
130	生产部 production department	领料 Material Requisition	使用错误的材料，和错误的数量，没有按照先进先出的原则 Using the wrong material (number) and wrong quantity; not in accordance to FIFO principle	产品返工或报废，产品质量问题无法追溯 Rework or scrap, quality issues will be difficult to trace	6	外包装无日期，品名等标识，仓管员未按照先进先出执行 No identification and indicating "Date, Part no., etc." on label; not following FIFO	2	仓库管理员收货并对产品的标识及数量等进行核对 Warehouse verify the quantity and identification of Part and quantity	2	24							
140	生产部 production department	组装 Assembly	1.组装间隙，错位，脱落等不良。 Gap, mismatch and dropping issue 2.漏装零配件。 Missing of components	产品不合要求 Does not meet requirements of product	6	作业方法不对 Incorrect of working method	2	组装作业指导书 Assembly Work Instruction	2	24							
150	生产部 production department	视频拍摄检查 Video Recording Check	视频无法清晰捕捉区域/角度 area/angle not able to capture clearly by video	导致产品返工，追溯困难 Parts need to rework, hard to trace	6	检验员疏忽 Staff negligence	1	视频检查前，包装人员拿起产品，对所有的面进行仔细检查。Before the video inspection, the packer picks up the part and carefully inspects all the sides.（零件必须以任何角度进行检查，不会指定角度。No angle will be specified and parts are subject to check at any angles.）	2	12	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		包装 Packaging	包装不能有效保护好产品。 Packaging does not effectively protect the part.	导致产品外观不良。重新返工。 Resulting in poor part appearance, rework again.	5	没能选用合适的包材。 Failed to choose suitable packaging material.	3	针对产品造型设计合适包材，包装经过自由落体验证后，确定能完好的保护产品后，才能批量使用。 Appropriate packaging materials are designed according to the part shape, the packaging can be used in batches only after it has been verified by free fall and can protect the part is intact.	3	45							
			包装产品过程磕碰不良。 The process of packaging parts is defective.	导致产品外观不良。重新返工。 Resulting in poor part appearance, rework again.	5	包装台外漏无防护，包装作业时容易磕碰产品。 The packaging table has no protection against leakage, it is easy for parts to be bumped during packaging operations.	3	包装台垫上海棉。 Cover the packaging table with foam.	3	45							
			包材用错。 Wrong packaging material used.	造成产品无法包装，或者包装后产品保护不到位 The part cannot be packaged or the part is not properly protected after packaging.	5	包装人员不清楚包材规格。 Packaging personnel do not know the packaging material specifications.	2	包材规格及用量写入包装指导书内，包材放入仓库固定库位，使用时由专人到库位领取。 The specifications and amount of packaging materials are written in the packaging instructions, the packaging materials are placed in a fixed location in the warehouse. When used, a designated person will pick them up at the location.	3	30							
160	仓库 warehouse	储存 Product storage	成品存储超过有效期 Expired shelf life of finished goods	影响产品性能 Affect function and performance	6	没有遵循先进先出原则 Failure to follow FIFO	2	物料接收章和先进先出管理 Receiving Stamp and FIFO Management	3	36							
170	仓库 warehouse	出货 Outgoing Shipment	发货错、少数量 The delivery is short of quantity	影响客户生产 Affect customer production line	6	没仔细核对发货单 Not checking the invoice carefully	2	发货单 invoice	4	45							
180	仓库 warehouse	发运 Forwarding despatch	发货错、少数量 The delivery is short of quantity	影响客户生产 Affect customer production line	6	没仔细核对发货单 Not checking the invoice carefully	2	发货单 invoice	4	45							
			产品受损 Products to receive damage	影响产品质量 Affect product quality	6	运输过程防护不当 Improper protection during transportation	2	产品防护管理程序 Preservation of product procedure	4	45							

HANSIN Production Quality FMEA SEVERITY RANKINGS						
用户后果(Customer Effect)		HANSIN Factory 制造/生产后果(Manufactory effect)		标准 (Criteria: Severity of Effect Defined)	Effect	评分 (Ranking)
潜在失效模式影响安全使用或包含不符合政府法规情形。失效发生时无警告	Potential failure mode affects safety or involves noncompliance with government regulation. Failure occurs without warning.	可能危及作业员 (机器或组装) 而无警告	Hurt operator (machine) without warning	May endanger operator. Failure mode affects safe vehicle operation and / or involves noncompliance with government regulation. Failure will occur WITHOUT warning.	Hazardous-without warning	10
潜在失效模式影响安全使用或包含不符合政府法规情形。失效发生时无警告	Potential failure mode affects safety issue or involves noncompliance with government regulation. Failure occurs with warning.	可能危及作业员 (机器或组装) 但有警告	Hurt operator (machine) with warning	May endanger operator. Failure mode affects safe vehicle operation and / or involves noncompliance with government regulation. Failure will occur WITH warning.	Hazardous-with warning	9
丧失基本功能 (产品不能运行, 但不影响安全性)	Loss of primary function (Product cannot be used but does not affect safety)	产品可能必须要 100% 丢弃 产线停止并停止装运	Product may be scrapped 100% stop line , stop shipment	Major disruption to production line. 100% of product may have to be scrapped. Vehicle / item inoperable, loss of primary function. Customer very dissatisfied.	Very High	8
主要功能降级 (产品可运行, 但性能层次降级)	Primary function reduced (product can be used, but functional preformance degrades)	产品可使用一部分 (少于100%) 必须被丢弃。 主要过程中出现偏差 (生产线速度降低或需要增加人力)	A part of product can be used, (less than 100%) may be scrapped. Major process has problem (production line speed will be slower or increase manpower)	Minor disruption to production line. Product may have to be sorted and a portion (less than 100%) scrapped. Vehicle operable, but at a reduced level of performance. Customer dissatisfied.	High	7
次要功能丧失 (产品可运行, 但便利等功能丧失)	Loss of minor function (product can be used but with loss in functions such as convenience)	产品使用必须在 100%返工之后	Must rework the 100% product off-line before use. A part of product may be scrapped	Minor disruption to production line. A portion (less than 100%) may have to be scrapped (no sorting). Vehicle / item operable, but some comfort / convenience item(s) inoperable. Customers experience discomfort.	Moderate	6
次要功能降低 (产品可运行, 但便利等功能降低)	Reduction of minor function (product can be used but with degradation in functions such as convenience)	一部分产品使用必须经过返工	A part of product must be rework off-line before use	Minor disruption to production line. 100% of product may have to be reworked. Vehicle / item operable, but some comfort / convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction.	Low	5
产品可使用, 但是外观或噪音等项目不合格, 并大多数 (>75%) 客户会发现这些缺陷	Product can be used but aspects such as cosmetic appearance and sound insulation doesn't meet spec; majority (>75%) user can detect these defects	产品使用必须在 100%在线返工之后	Must rework the 100% product on the production line before use	Minor disruption to production line. The product may have to be sorted and a portion (less than 100%) reworked. Fit / finish / squeak / rattle item does not conform. Defect noticed by most customers.	Very Low	4
产品可使用, 但是外观或噪音等项目不合格, 并许多 (50%) 客户会发现这些缺陷	Product can be used but aspects such as cosmetic appearance and sound insulation doesn't meet spec; many (50%) user can detect these defects	一部分产品使用必须经过在线返工	A part of product must be rework on the line before use	Minor disruption to production line. A portion (less than 100%) of the product may have to be reworked on-line but out-of-station. Fit / finish / squeak / rattle item does not conform. Defect noticed by average customers.	Minor	3
产品可使用, 但是外观或噪音等项目不合格, 并少数 (<25%) 有辨别能力客户会发现这些缺陷	Product can be used but aspects such as cosmetic appearance and sound insulation doesn't meet spec; some (<25%) user can detect these defects	对过程, 作业或作业员带来轻微不便	Make inconvenience for process , operation or operator	Minor disruption to production line. A portion (less than 100%) of the product may have to be reworked on-line but in-station. Fit / finish / squeak / rattle item does not conform. Defect noticed by discriminating customers.	Very Minor	2
没有可识别的后果	No identifiable effect	没有可识别的影响	Even operator find out the defect , no actions needed	No effect.	None	1

RPN得分与对策基准对照表 (RPN value and corrective actions matrix)			
等级 (Grade)	得分 (RPN value)	对策基准 (Action standard)	备注 Notes
S	≥512	设计变更对策 (Design change)	
A	≥216	一定要下对策 (Prevent action required)	
B	≥100	尽量下对策 (Take actions if possible)	
C	≥27	斟酌下对策 (Take action considering manufacturing impact)	
D	<27	视情况下对策 (Take action considering the risk)	
Occurance>7 or Severity>7 or Detection>7		一定要下对策 (Preventive action required, it is imperative to act regardless of the RPN value)	列入A (Same as A)

HANSIN Production Quality FMEA OCCURRENCE EVALUATION RANKINGS						
失效可能性 (Probability of Failure)		发生可能性 (Possible Failure Rates)	Cpk	PPM	%	(评分) Ranking
Very High: Failure is almost inevitable	很高:	1 in 2	< 0.33	Persistent failures, >= 100,000 ppm.	>= 10	10
	失效几乎是必然的	1 in 3	< 0.33	>= 50,000 ppm < 100,000 ppm	5	9
High: Generally associated with processes similar to previous processes that have often failed	高: 发生在与之前经常有失效的类似站别	1 in 8	< 0.51	>= 20,000 ppm < 50,000 ppm	2	8
		1 in 20	< 0.67	Occurrence about 1 per month or >= 10,000 ppm < 20,000 ppm	1	7
Moderate: Generally associated with processes similar to previous processes which have experienced occasional failures, but not in major proportions	中等: 发生在与之前偶尔有失效的类似站别	1 in 80	< 0.83	Occasional Failure of about 1 every 3 months or >= 5,000ppm < 10,000ppm	0.5	6
		1 in 400	< 1	Occurrence about every 6 to 12 months or >= 2,000 ppm < 5,000 ppm	0.2	5
		1 in 2,000	< 1.17	1000 ppm	0.1	4
Low: Isolated failures associated with similar processes	低: 孤立的失效发生在大多数类似的站别	1 in 15,000	< 1.33	500 ppm	0.05	3
Very Low: Only isolated failures associated with almost identical processes	非常低: 孤立的失效发生在特定站别	1 in 150,000	< 1.5	100 ppm	0.01	2
Remote: Failure is unlikely. No failures ever associated with almost identical processes	极低: 失效可能性低。在大多数的过程中都没有发生过的失效	1 in 1,500,000	< 1.67	10 ppm	<=0.001	1

可侦测 (Detection)		检查类型			标准：制程管制之可能检出率 Criteria: Likelihood the existence of a defect will be detected by test content	评分 (Ranking)
		系统放错 SFIS	测量 Measure	人工检查 Visual		
Almost Impossible	几乎不可能			○	确定无法探测，也没有检查。 (No way to detect and inspect)	10
Very Remote	很渺小			○	现在控制方法不可能探测，仅能以间接或随机检查来达到控制 (Current control processes cannot detect; can only be detected via indirect or sampling methods)	9
Remote	渺小			○	现在控制方法只有很小机会去探测，仅能以目视检查来达到控制 (Current control processes can detect with a low possibility; can be detected with visual inspection)	8
Very Low	很低			○	现在控制方法只有很小机会去探测，现场无法察觉，需要工程师利用仪器且复杂手续方能发现，或通过双重目视检查来达到控制 (Current control processes can detect with a low possibility; cannot be detected on-site and requires engineers to use equipment with complex procedures or repeated visual inspection to detect)	7
Low	低		○	○	现在控制方法可能可以探测，但失效无法察觉或不能轻易被发现，只能用图表方法（比如：SPC）来达到控制 (Current control processes may be able to detect but loss in efficiency is difficult if not impossible to detect; control can be achieved only with graphical methods such as SPC chart)	6
Moderate	中等		○		现在控制方法可能可以探测，但只能在检验时由其他测量仪器设备方能发现 (Current control processes may be able to detect but gauge or measuring instruments must be used to detect)	5
Moderately High	中上	○	○		现在控制方法有很好的机会去探测，可在后续作业中探测失效，或通过作业前准备和首件的测定检查探测和失效 (Current control processes can detect at a high chance; failure can be detected in the subsequent operation or through pre-operations preparation and during FA inspection)*	4
High	高	○	○		现在控制方法有很好的机会去探测，本工序作业可发现失效，或后续作业中可被探测失效 (Current control processes can detect at a high chance; failure detection can occur in the current operation or the the subsequent operation)	3
Very High	很高	○	○		现在控制方法几乎可以探测，现场制造设备即可自动判断且发现，失效产品不能被通过 (Current control processes can detect almost all the time; on-site production facilities can determine and detect failure automatically. Unqualified products shall not pass.)	2
Almost Certain	几乎肯定	○			现在控制方法肯定可以探测，已设计了防错，失效产品不会发生 (Current control processes can definitely detect; prevention ensures that failed products do not occur)	1

* Note: Identical to Manual except for Rankings of 6 and 4. Words "OR gauging performed on setup and first piece check" moved from a detection of 4 to a detection of 6