

PRODUCTION REALIZATION

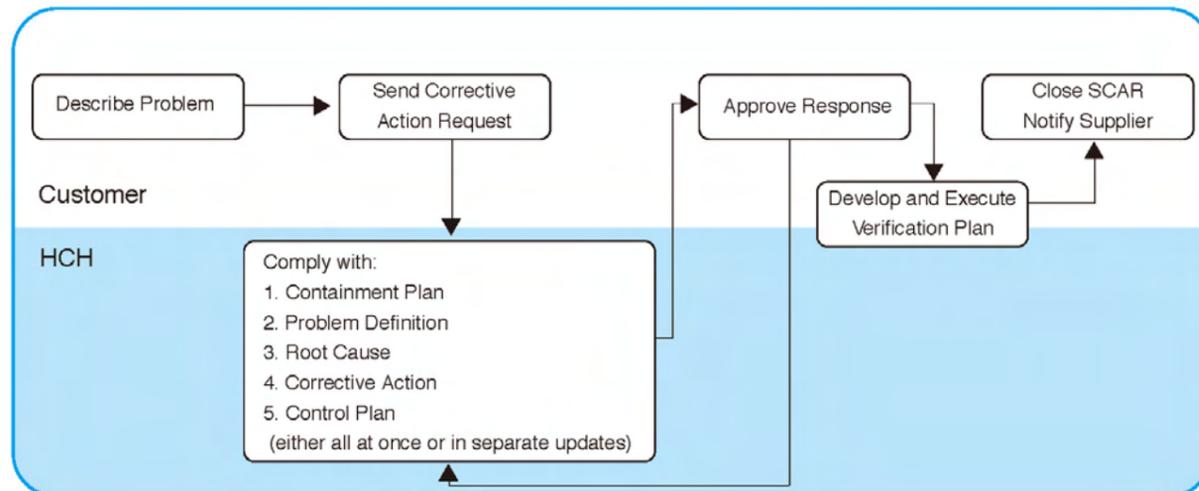
In planning product realization, HCH Group will determine the following, as appropriate:

- Quality objectives and requirements for the product.
- The need to establish processes, documents, and provide resources specific to the product.
- Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.
- Records needed to provide evidence that the realization processes and resulting product could meet customer requirements and references to its technical specifications shall be included in the planning of product realization as a component of the quality plan.

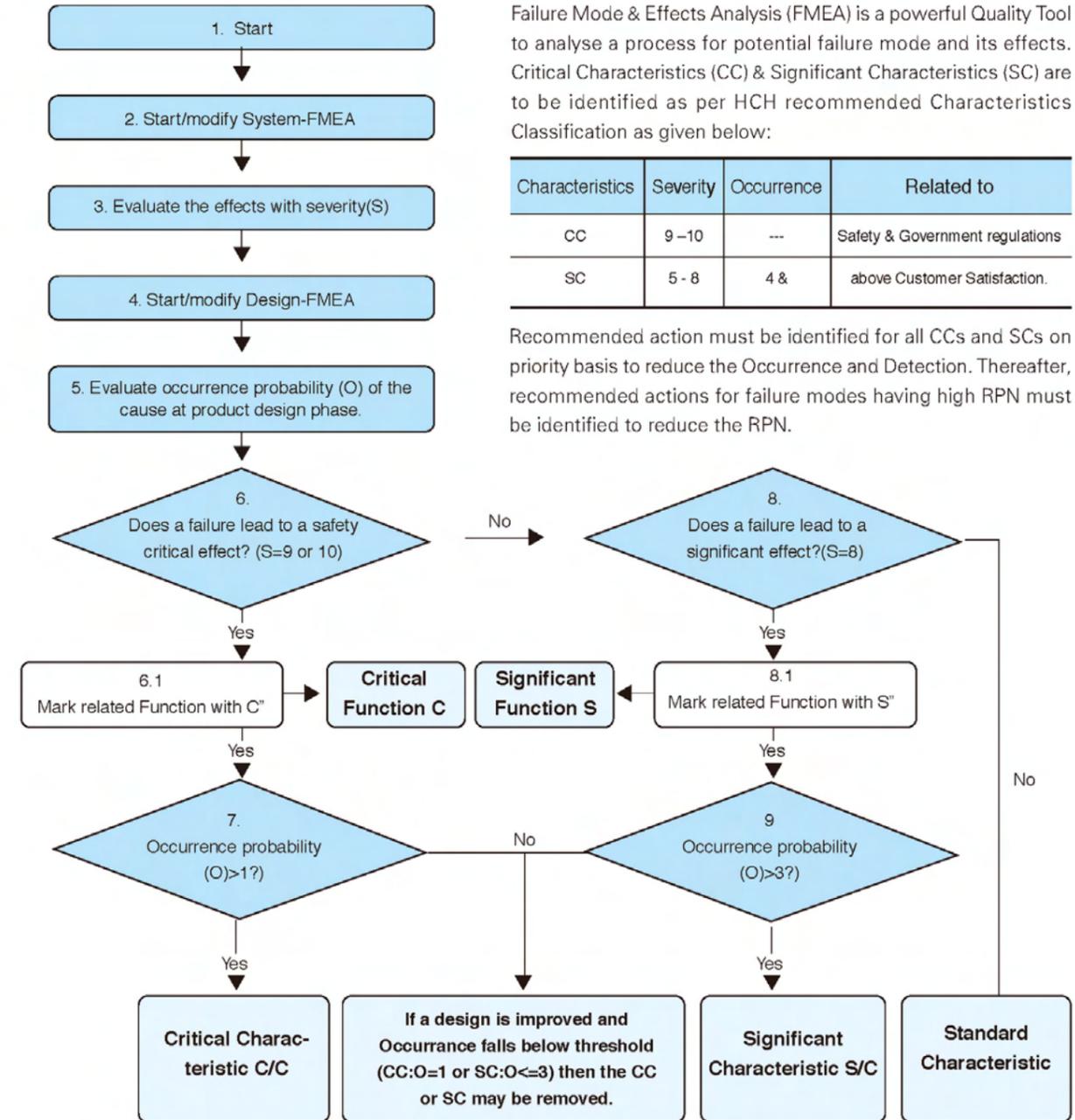
Acceptance criteria	HCH Group will define the acceptance criteria and, where required, approved by the customer. For attribute data sampling, the acceptance level shall be zero defects.
Change control	HCH has to set up a process to control and react to changes that impact product realization. Changes shall be validated before implementation.
Zero defect products	In theory, this is the description of an ideal state. In reality though, we are constantly confronted with different kinds of disturbances that dramatically increase the risk of defects in manufactured products.
Traceability	Where traceability is a requirement, we control and record the unique identification of our products. HCH has retain manufacturing records for a minimum of 3 years, unless otherwise specified,
Preventive action	HCH Group shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.
Problem solving	HCH Group shall have a defined process for problem solving leading to root cause identification and elimination. Records of these analyses shall be kept and made available upon request.
Corrective action	HCH Group shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

● Corrective Action Request

This procedure applies to quality failures and delivery issues with production parts and raw materials detected at HCH's Customer.



FMEA:



Failure Mode & Effects Analysis (FMEA) is a powerful Quality Tool to analyse a process for potential failure mode and its effects. Critical Characteristics (CC) & Significant Characteristics (SC) are to be identified as per HCH recommended Characteristics Classification as given below:

Characteristics	Severity	Occurrence	Related to
CC	9 -10	---	Safety & Government regulations
SC	5 - 8	4 &	above Customer Satisfaction.

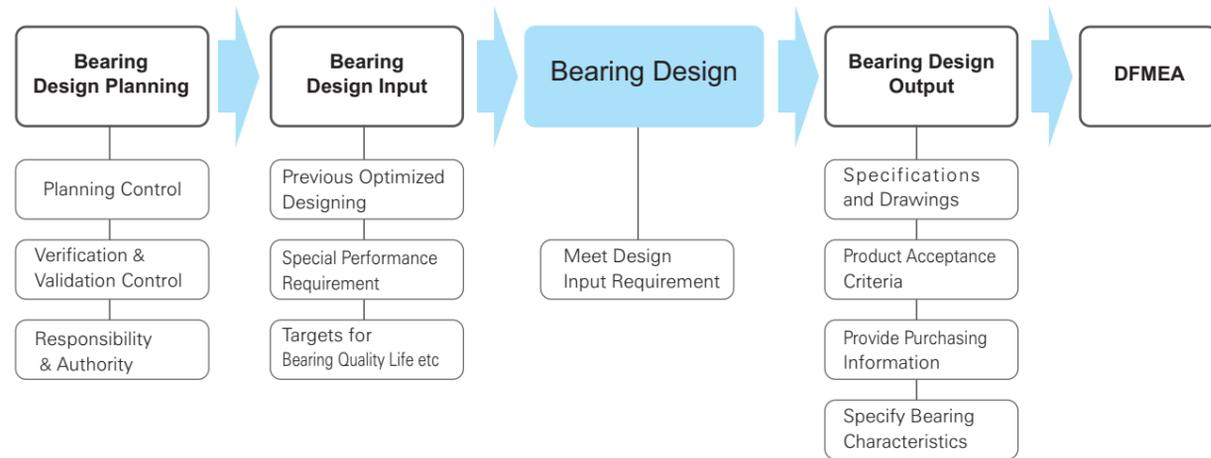
Recommended action must be identified for all CCs and SCs on priority basis to reduce the Occurrence and Detection. Thereafter, recommended actions for failure modes having high RPN must be identified to reduce the RPN.

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA)

No.	Process Function Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s) of Failure	Occur	Current Process Controls Prevention	Current Process Controls Detection	Detect	R.P.N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
														Actions Taken	Sev	OCC	Det	R.P.N.
											0					0		
											0					0		
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DFMEA:

A Design or Concept FMEA is a systematic approach (used by the design responsible team), to assure that potential design failure modes and associated causes have been considered and addressed.



A PFMEA is a living document and needs to be reviewed and updated as new failure modes are discovered. A PFMEA is used to identify potential weak areas in the manufacturing and assembling process. Cross-functional teams should be organized to study each step of process for possible failure modes, effects of failures, and potential causes. Countermeasures must be provided for failure modes with high Risk Priority Numbers (RPN). Also, regardless of the resultant RPN, special attention must be given when the severity is high.

DFMEA Severity Ranking Table :

Design FMEA : Severity of Effect		
Effect	Criteria	Ranking
Hazardous without warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and / or involves noncompliance with government regulation without warning.	10
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and / or involves noncompliance with government regulation with warning.	9
Very High	Vehicle / item inoperable, with loss of primary function.	8
High	Vehicle/ item operable, but at reduced level of performance. Customer very dissatisfied.	7
Moderate	Vehicle / item operable, but Comfort / Convenience item(s) inoperable. Customer dissatisfied	6
Low	Vehicle / item operable, but Comfort / Convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction.	5
Very Low	Fit & Finish / Squeak & Rattle item does not conform. Defect noticed by most customers.	4
Minor	Fit & Finish / Squeak & Rattle item does not conform. Defect noticed by average customers.	3
Very Minor	Fit & Finish / Squeak & Rattle item does not conform. Defect noticed by discriminating customers.	2

DFMEA Occurrence Ranking Table :

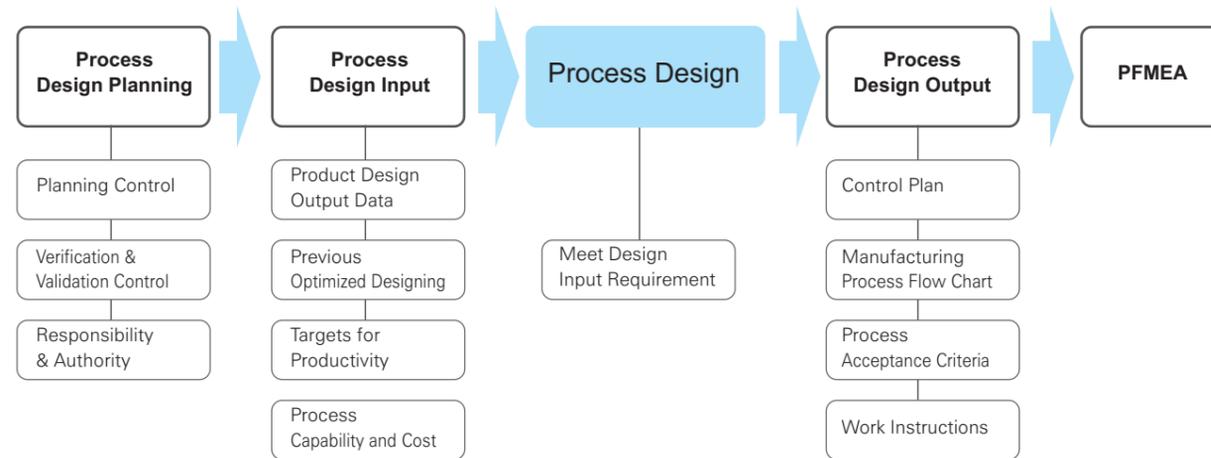
Probability of Failure	Possible Failure Rates	Ranking
Very High: Persistent Failures	>= 100 per thousand vehicles/ items	10
	50 per thousand vehicles / items	9
High: Frequent Failures	20 per thousand vehicles / items	8
	10 per thousand vehicle / items	7
Moderate: Occasional Failures	5 per thousand vehicle / items	6
	2 per thousand vehicle / items	5
	1 per thousand vehicle / items	4
Low: Relatively Few Failures	0.5 per thousand vehicle / items	3
	0.1 per thousand vehicle / items	2
Remote: Failure is unlikely	<= 0.01 per thousand vehicle / items	1

DFMEA Detection Ranking Table :

Design FMEA : Severity of Effect		
Detection	Criteria	Ranking
Absolute Uncertainty	Design Control will not and / or cannot detect a potential cause /mechanism and subsequent failure mode; or there is no Design Control	10
Very Remote	Very remote chance that the Design Control will detect a potential cause / mechanism and subsequent failure mode	9
Remote	Remote chance that the Design Control will detect a potential cause / mechanism and subsequent failure mode	8
Very Low	Very remote chance that the Design Control will detect a potential cause mechanism and subsequent failure mode	7
Low	Low chance that the Design Control will detect a potential cause / mechanism and subsequent failure mode	6
Moderate	Moderate chance that the Design Control will detect a potential cause / mechanism and subsequent failure mode	5
Moderately High	Moderately high chance that the Design Control will detect a potential cause / mechanism and subsequent failure mode	4
High	High chance that the Design Control will detect a potential cause / mechanism and subsequent failure mode	3
Very High	Very high chance that the Design Control will detect a potential cause / mechanism and subsequent failure mode	2
Almost Certain	Design Control will almost certainly detect a potential cause / mechanism and subsequent failure mode	1

Process Failure Modes and Effects Analysis (PFMEA)

A Process FMEA is a systematic approach used by a manufacturing responsible team to assure that potential process related failure modes and their associated causes have been considered and addressed.



Severity Ranking Table :

Effect	(Customer Effect)	(Manufacturing/Assembly Effect)	Ranking
Hazardous without warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning	Or may endanger operator (machine or assembly) without warning.	10
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning	Or may endanger operator (machine or assembly) with warning.	9
Very High	Vehicle/item inoperable (loss of primary function).	Or 100% of product may have to be scrapped, or vehicle/item repaired in repair department with a repair time greater than one hour.	8
High	Vehicle/item operable but at a reduced level of performance. Customer very dissatisfied.	Or product may have to be sorted and a portion (less than 100%) scrapped, or vehicle/item repaired in repair department with a repair time between a half hour and an hour.	7
Moderate	Vehicle/item operable but Comfort/Convenience item(s) inoperable. Customer dissatisfied.	Or a portion (less than 100%) of the product may have to be scrapped with no sorting, or vehicle/item repaired in repair department with a repair time less than a half-hour.	6
Low	Vehicle/item operable but Comfort/Convenience item(s) operable at a reduced level of performance	Or 100% of the product may have to be reworked, or vehicle/item repaired offline but does not go to repair department.	5
Very low	Fit and finish/Squeak and Rattle item does not conform. Defect noticed by most customers (greater than 75%).	Or the product may have to be sorted, with no scrap, and a portion (less than 100%) reworked.	4
Minor	Fit and finish/Squeak and Rattle item does not conform. Defect noticed by 50% of customers.	Or a portion (less than 100%) of the product may have to be reworked, with no scrap, online but out of station.	3
Very Minor	Fit and finish/Squeak and Rattle item does not conform. Defect noticed by discriminating customers (less than 25%)	Or a portion (less than 100%) of the product may have to be reworked, with no scrap, online but in station.	2
None	No discernible effect	Or slight inconvenience to operation or operator, or no effect.	1

The final customer should always be considered first. If both occur, use the higher of the two severities.

Occurrence Ranking Table :

Probability of Failure	Likely Failure Rates	Ppk	Ranking
Very High: Persistent Failures	>= 100 per thousand pieces	<0.55	10
	50 per thousand pieces	>/=0.55	9
High: Frequent Failures	20 per thousand pieces	>/=0.78	8
	10 per thousand pieces	>/=0.86	7
Moderate: Occasional Failures	5 per thousand pieces	>/=0.94	6
	2 per thousand pieces	>/=1.00	5
	1 per thousand pieces	>/=1.10	4
Low: Relatively Few Failures	0.5 per thousand pieces	>/=1.20	3
	0.1 per thousand pieces	>/=1.30	2
Remote: Failure is unlikely	</= 0.01 per thousand pieces	>/=1.67	1

Detection Ranking Table

Detection	Criteria	Inspection Type			Suggested Range of Detection Methods	Ranking
		A	B	C		
Almost Impossible	Absolute certainty of nondetection			X	Cannot detect or is not checked	10
Very Remote	Controls will probably not detect.			X	Control is achieved with indirect or random checks only	9
Remote	Control has poor chance of detection.			X	Control is achieved with visual inspection only	8
Very Low	Controls have poor chance of detection			X	Control is achieved with double visual inspection only	7
Low	Controls may detect			X	Control is achieved with charting methods, such as SPC (Statistical Process Control)	6
Moderate	Controls may detect		X		Control is based on variable gauging after parts have left the station, or Go/No Go gauging performed on 100% of the parts after parts have left the station	5
Moderately High	Controls have a good chance to detect.	X	X		Error detection in subsequent operations, OR gauging performed on set up and first piece check (for set-up causes only).	4
High	Controls have a good chance to detect.	X	X		Error detection in station, OR error detection in subsequent operations by multiple layers of acceptance: supply, select, install, verify. Cannot accept discrepant part.	3
Very High	Controls almost certain to detect	X	X		Error detection in station (automatic gauging with automatic stop feature). Cannot pass discrepant part.	2
Very High	Controls certain to detect	X			Discrepant parts cannot be made because item has been error-proofed by process/product design.	1

Manufacturing Process Flow Diagram / Map (MAP)

The Manufacturing Process Flow Chart is a graphic representation of the current or proposed sequence of manufacturing process flow. Typically it would start from incoming material inspection to packing and pre-dispatch inspection. It is used to emphasize the variation sources impact on the process. The flow chart helps to analyze the total process rather than individual steps in the process. The flow chart assists with conducting the FMEA and designing the Control Plan.

PROCESS FLOW DIAGRAM / MAP			
Part No. & Rev:		Date Submitted:	
Spec. No. & Rev:		Date Approved:	
Part Name:		Diagram Revision:	
Manufacturing Process:		Chart By:	

Capacity Demonstration Review (CDR)

The CDR is a tool to verify that the HCH's production process can meet customers' planning volumes with quality parts. If the production process failed to produce enough quality parts to meet the quoted tool capacity on the tooling order, HCH will continue to work in improving process capability.

Capacity Demonstration Review(CDR)						
Program:				Planned Cycle Time(min/part):		
Planned # Shifts:				Total Available Time(minutes):		
Operation	Hour	Good Parts	Rejects (Rework+Scrap)	Unplanned Downtime(min)	Planned Downtime(min)	Comments
	1					
	2					
	3					
	4					
Total:						
Equipment Availability:	A.Total Available Time(minutes):					
	B.Planned Downtime(minutes):					
	C.Net Available Time:(A-B)					
	D.Unplanned Downtime (minutes):					
	E.Operating Time: (C=D)					
Performance Efficiency:	F.Equipment Availability (E/C x 100)					
	G.Total Parts Run: (Include both good and bad parts)					
	H.Planned Cycle Time (min/part)					
Quality Rate:	I.Performance Efficiency: (G x H)/E*100					
	J.Total Defects (# parts): (Rework+Scrap)					
Overall Equipment Effectiveness:	K.Quality Rate: (G-J)/G x 100					
	Equipment Availability x Performance Efficiency x Quality Rate x 100					

Control Plan

HCH has developed a systematic control plan at its manufacturing, raw material purchasing as well as the components supplied. It is consistent with its HCH design FMEA and Manufacturing FMEA outputs. In the control plan, the controls that used for the Manufacturing control are listed including control characteristics, required standards, methods for monitoring, the specified reaction plan, as well as the customer-required information, etc.

Control Plan													
				Issue Date:		Effectivity Date:		Rev.:		Revision Date			
Part No & Rev.:				Spec No & Rev.:				Part Name:					
#	Operation/ Process	Machine, Cavity, etc	product	process	Key/ Standard Charac.	Specification	Tolerance	Inspection Device	Size	Freq.	Control Method	Cpk	Control Location Reaction Plan

6.4 Overview of Part Qualification Requirements (PQR)

The Part Qualification Requirements document defines the process, responsibilities and deliverables for introducing new or revising components to customers. It is intended to help HCH successfully achieve the quality of the product design.

Part Qualification Requirements			
A Part Information			
Part Number	Part Name	Revision Level	Sites Used
B Must comply with Critical Characteristics as identified on part drawing and the following:			
Ref #	Specification	Ref #	Specification
C Qualification Requirements			
<input type="checkbox"/> Sample Pieces Number total pieces required: Number of pcs.First Article Insp. Number master samples required:		<input type="checkbox"/> Initial Process Capability Studies Number parts for capability study	
<input type="checkbox"/> Material Test / Certification Results (Per drawing or specification)		<input type="checkbox"/> Capacity Demonstration (Run at rate)	
<input type="checkbox"/> Checking Aids (Fixtures, special gages, etc.)		<input type="checkbox"/> Customer Specific Requirements (Per drawing or specification; attach to sheet)	
<input type="checkbox"/> Failure Modes & Effects Analysis (FMEA) <input type="checkbox"/> Design (DFMEA) <input type="checkbox"/> Process (PFMEA)		<input type="checkbox"/> Measurement System Analysis Gage R&R Max allowable results:	
<input type="checkbox"/> Process Flow Diagram		<input type="checkbox"/> Control Plans	
<input type="checkbox"/> Performance / Reliability Test Results (Per drawing or specification; attach to sheet)		<input type="checkbox"/> Dimensional and Attribute Inspection Results	
<input type="checkbox"/> Qualified Lab Documentation (Per drawing or specification; attach to sheet)		<input type="checkbox"/> Design Records (Marked Drawing)	
<input type="checkbox"/> Bulk Materials Requirements		<input type="checkbox"/> Process and/or Engineering Change Documents	
<input type="checkbox"/> RoHS Certification		<input type="checkbox"/> Appearance Approval Reports	
<input type="checkbox"/> Early Launch Containment		<input type="checkbox"/> Component Process Audit	
		<input type="checkbox"/> Special Instructions (See Attached)	