



INITIAL PART CONTROL RULE(CHANGE POINT)

ISD-QA-043



RULE

Department

Quality Assurance

DATE: 9.09.2019

Area

Overall

Issue: 02

Revision: 00

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PURPOSE:-

The purpose of this rule is to assure/maintain the product quality in case of any change in people, manufacturing process, manufacturing methods & products (4M) at the production stage of Musashi Group.

SCOPE:-

All in-house manufactured products and process, including event products of new model at the start-up stage (including mass produced first -time products), mass produce products & service parts.

DEFINATION OF INITIAL PART:-

The very first product (lot/batch) which are produced immediately after the change point .

CHANGE POINT MANAGEMENT:-

• Categorization of IPP & Conditions

- (1) Specification change IPP:- Change of spec which is based on "Spec change rule " of customer.
 - (2) Quality improvement IPP:- Change in method of controlling as an improvement against any quality trouble.
 - (3) Self-controlled IPP:- Internal change in 4M for improvements/betterment.
 1. Before initiating IPP the effect of Improvement should be clarified & Evaluation to be done by GM-Production division in terms of QCD at the time of proposal.
 2. All evaluation documents shall be determined (as per Annex. 1 & 2) & if req. share with customer in advance.
 3. Give prior information to customer (Advance IPP) before 3 months of change point /as per customer req.
 4. Risks for change points shall be assessed, and appropriate measures shall be taken in advance.
 5. Highly important(critical) change point to be shared with MSI Quality Assurance Division.
 - (4) General IPP :-Change which occurs in NPD events at start up stage, mass production stage, products or service parts or customer request.
- ##### • Control of Initial Flow (product)
- Verification of stable production & consistent quality have to be maintained after implementing IPP by setting the standard for control period, evaluation items & conditions of release(Refer Annex-3).

• Control & Traceability of IPP

- 1.IPP format to be attached on the product based on the customer requirements regarding (1)/(2)/(3) & (4).
- 2.Traceability of change point to be control as per "IPP Monitoring sheet" .
- 3.Record of detail to be maintained if IPP received in supplier parts or customer supplied parts .

• Storage of IPP

Maintain the record of IPP as specified by organization/Customer.

SUDDEN (UNEXPECTED) CHANGE POINT MANAGEMENT:-

• Handling

- (1) Sudden(unexpected) change point in process(4M) should be handled based on "Abnormality handling rule" to ensure correct treatment & traceability.
- (2) Immediate information to be shared with customer in case of any abnormal delivery (or possibility) of product.
- (3) In case of change in Men (new employee, support personnel from other process, change for holiday or accident etc.) record should be maintained in log book & the evidence of confirmation of result should be retained.
- (4) Implement the Quality check to prevent the flow of defective parts to customer before and after the change.
- (5) Preventive actions shall be taken by recording the change point in the active call system and change control sheet and analyzing the cause of abnormality to be reflected in the process.
- (6) In case of possibility of rework (as per customer satisfaction) ,it should be done following the "Rework procedure" , the product should be disposed if rework is not possible.

02	00	Global change point requirement added	9.09.2019
01	07	Customer information before 3 month	25.01.2018
Issue	Revision	Reason for change	Date

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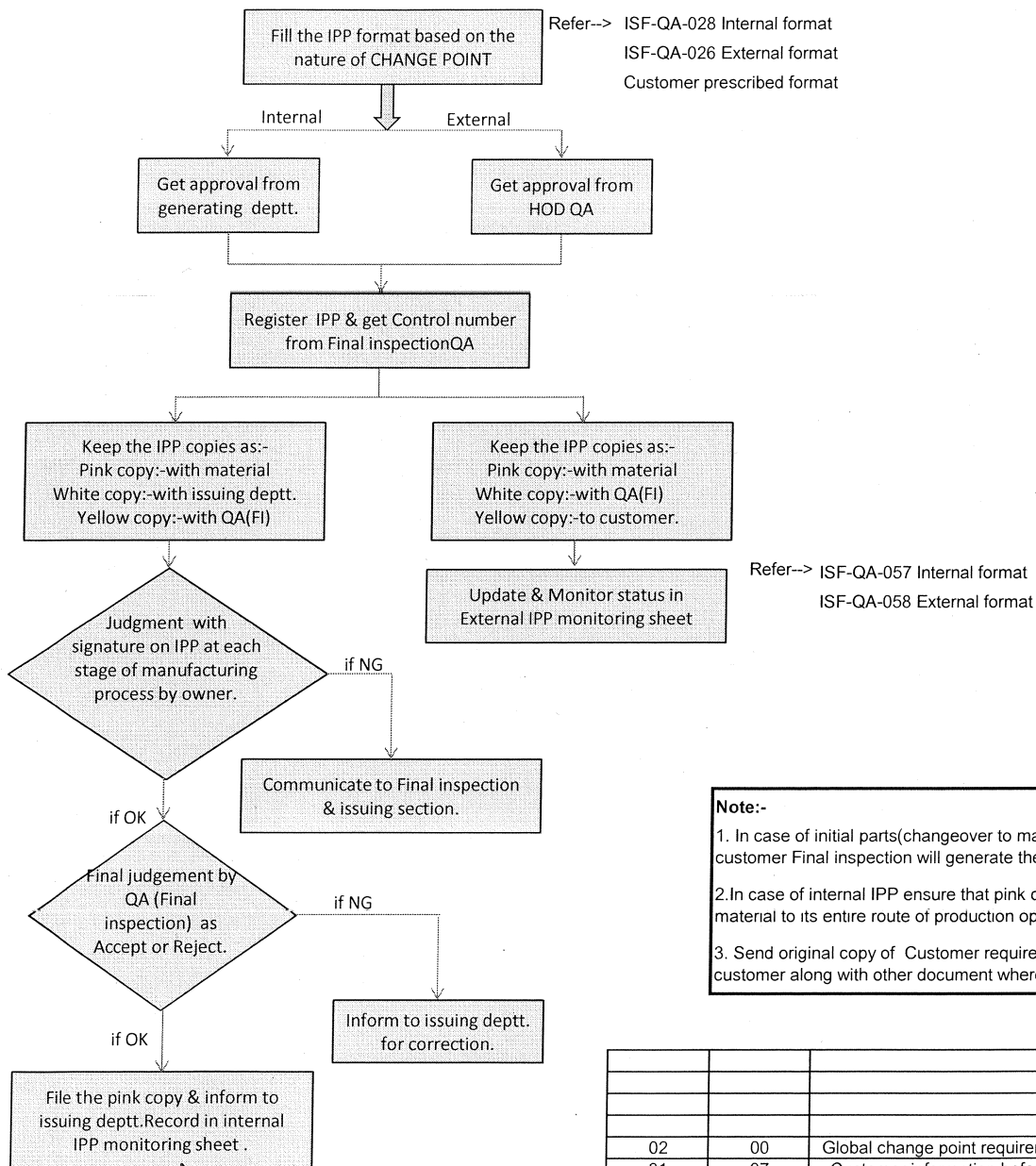
Revision: 00

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JUDGEMENT TO SHIFT TO MASS PRODUCTION

- (1) After confirmation of production preparedness & quality evaluation without any non conforming the changeover to mass production will be done.
- (2) Refer the **Annex. 1 & 2** for evaluation items & IPP then contact to customer.
- (3) During submission of IPP any instruction from customer to be followed.

IPP METHODOLOGY:-



02	00	Global change point requirement added	9.09.2019
01	07	Customer information before 3 month	25.01.2018
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INITIAL PART CONTROL RULE(CHANGE POINT)-ANNEXURE-1

ISD-QA-043



RULE

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Evaluation items of IPP

Evaluation item Content	Content
Process capability	① : Cpk after changing shall be better than that of before changing. (Cpk of key quality characteristics must be inspected.)
Validity check	① : Spec test (if required) ② : 9 point check at heat treatment (3-cycle evaluation) ③ : Hardness, structure, case depth, grain, decarburization and film thickness ④ : Fiber flow and crack ⑤ : Appropriateness for setting conditions ⑥ : Amount of distortion (tooth profile, inner/outer diameter, dimensions, etc.) ⑦ : Implementation of MSA (change of inspection method) ⑧ : Appropriateness for the lifespan of dies, cutting tools, and dress interval ⑨ : Roughness of sliding surface (3 cycle evaluation) ⑩ : Packaging evaluation (Dent, rust-proof, and packaging standard)
P-FMEA	① : P-FMEA shall be created or reviewed.
Inspection of IPP	① : Lay out or complete dimensional inspection (n=1) ② : Inspection of IPP by n=5 (n=1 for break test)
Document	① : Creation or review of control plan ② : Creation or review of work standard ③ : Creation or review of operation standard
QAV2	① : QAV2 shall be conducted as specified according to IPP rank. ② : Work environment, logistics, measurement tools, 5S, etc.
Others	① : Evaluation items shall be added if there are any special characteristics in IPP. ② : Additional items shall be evaluated in case of requests from the customer

Note:- 1.Evaluation items shall be added if there are any special characteristics in IPP based on opinion of experts .

2.Additional items shall be evaluated in case of requests from the customer.

3.Nonconformities detected in QAV2 shall be closed before shifting to mass production.

02	00	Global change point requirement added	9.09.2019
01	07	Newly made -Evaluation item list	25.01.2018
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INITIAL PART CONTROL RULE(CHANGE POINT)-
ANNEXURE-2

ISD-QA-043

Annexure-2

ANALYSE-Z										DATE: 9.09.2019		Approval		Premise to conduct QAV-2							
RULE		Department Area		Quality Assurance Overall		Issue: 02		Revision: 00		Process capability		Validity check		P-FMEA		Document		Each site		Report	
Category	Item	Situation		Explanation		Implement if requested by customer		Implement if requested by customer		Implement if requested by customer		Implement if requested by customer		Implement if requested by customer		Implement if requested by customer		Implement if requested by customer		Implement if requested by customer	
Specification change	Spec change	• Spec change for customer request		Based on spec change No.		Based on corrective action		Based on corrective action		Based on corrective action		Based on corrective action		Based on corrective action		Based on corrective action		Based on corrective action		Based on corrective action	
	Quality Improvement	• Quality improvement is implemented based on the request of the customer		Internal drawing design or spec is changed (no change in customer drawing)		Experienced similar products/process		Experienced similar products/process		Experienced similar products/process		Experienced similar products/process		Experienced similar products/process		Experienced similar products/process		Experienced similar products/process		Experienced similar products/process	
	Self-controlled IPP	• New supplier (including addition of manufacturing plant of current supplier)		• Change of supplier (including relocation of manufacturing plant of current supplier)		• Change of supplier (including relocation of manufacturing plant of current supplier)		• Change of supplier (including relocation of manufacturing plant of current supplier)		• Change of supplier (including relocation of manufacturing plant of current supplier)		• Change of supplier (including relocation of manufacturing plant of current supplier)		• Change of supplier (including relocation of manufacturing plant of current supplier)		• Change of supplier (including relocation of manufacturing plant of current supplier)		• Change of supplier (including relocation of manufacturing plant of current supplier)		• Change of supplier (including relocation of manufacturing plant of current supplier)	
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Regarding change points having "mark", the organization shall report to the customer in advance in case of changing items specified in the control plan.
If the organization has difficulty in determining whether they need advance notice to the customer or not, they shall discuss with their quality assurance division and determine it.
In order to appropriately control environmental hazardous substances, if there are changes in components or attached materials on the product, the organization shall proceed the necessary procedure during PP application following the customer requirement and environmental regulations.

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02		00		Global change point requirement added		9.09.2019	
01		07		Newly made Evaluation item list		25.01.2018	



INITIAL PART CONTROL -ANNEXURE-3

ISD-QA-043



RULE

Department

Quality Assurance

DATE: 9.09.2019

Area

Overall

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1) Initial Flow Control

Initial flow control is a concept of exercising special and additional controls after the start of mass production for determining whether mass production can be continued in the current process or not.

1) Designation of Initial Flow Control

Referring the below table, QA head shall judge the necessity of initial flow control, and specify the subjected part/model & period of IFC before start of mass production. If customer specified IFC requirement is available, same shall be followed.

Category of Initial Parts	Critical Control	Control Period of Initial Flow	Assigned Div;	Personnel
New Model parts	3 months	QA	Div manager QA
Spec Change Parts	Available	one month	QA	Div manager QA
	Not Available	--		
New Supplier's Parts	Available	one month	QA	Div manager QA
	Not Available	--		
Process Flow Change Parts	Available	one month	QA	Div manager QA
	Not Available	--		
Machine Change Parts	Available	one month	QA	Div manager QA
	Not Available	--		

Assigned Div. Manager shall create "Notification of Initial Flow Control" (ISF-QA-065 A-1) by every part that is subject to initial flow control, and notify it of relevant divisions (refer to Article 6-2) at the start of mass production.

2) Implementation and Release/termination of Initial Flow Control

QA dept (NPD QA for new model parts / In-process QA for change in mass production parts) shall raise "Notification of Initial Flow Control" for parts/model subjected to initial flow control, and notify it of relevant divisions (refer to Article 6-2) at the start of mass production.

QA department shall determine the control items & control method "IFM Activity Plan" "ISF-QA-065" and inform concern dept (Prod, PE, Maint, etc) about the Initial Flow Model in advance of mass production, and shall direct the implementation of Initial Flow Control

QA department shall regularly monitor the IFC activities, and at the end of designated period, if all the requirement of releasing IFC are satisfied, and corrective action for all the issues are taken, then QA head shall release/terminate the initial flow control by signing off "Initial Flow Control" "ISF-QA-065".

If the IFC cancellation requirement are not satisfied, the IFC shall be keep extended by 1 month, till it satisfy the termination requirement.

Item of Initial Flow Control	Method/Frequency of Confirmation	Requirements of Releasing
Critical Control Item		
• Appearance Control Item	100% Visual Inspection	Carrying-in defect has not been found.
• Priority Control Item	Frequency: Two times of general ins	Carrying-in defect has not been found.
Number of Carrying-in Defect	Customer's Complaints	The target has been achieved.
Process Capability	Once a Month	Cpk \geq 1.33
Customer's Direction	—	The requirements has been fulfilled.
Issues at Prod. Preparation Stage	—	Measures and effectiveness confirmed, and judged OK
Issues during Initial Flow	—	Measures and effectiveness confirmed, and judged OK

Note: Abnormalities observed during initial flow control shall be treated as per CAPA rule. And the measures shall be completed and effectiveness shall be confirmed during initial flow period.

If process capability is insufficient, measures shall be taken to prevent outflow of NG parts and ensure quality assurance.

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01	07	Newly made -Evaluation item list	25.01.2018
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