

*Supplier Quality Assurance  
Manual*

**MIKUNI CORPORATION**

<b>MID-Q06-002</b>	<b>Quality Management System Standard</b>	<i>Established</i>	<i>March 14, 2016</i>
	<i>Supplier Quality Assurance Procedure</i>	<i>6th Edition</i>	<i>07/06/2022</i>

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*Form 6-2 Part Inspection Standard (A3 size)*

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## **1. Introduction**

### **1.1 Purpose**

*This Supplier Quality Assurance Procedure defines the quality assurance requirements concretely so that suppliers to do the business with Mikuni Corporation (Hereinafter referred to as "Mikuni") supply the parts assured quality on basis of "Basic Contract Document" and "Quality Assurance Agreement" to be concluded between Mikuni and supplier.*

### **1.2 Scope**

*This Supplier Quality Assurance Procedure shall be applied to all parts ordered by Mikuni from suppliers & sub supplier who supply those parts. In addition, application of individual requirements as defined in this Supplier Quality Assurance Procedure shall be described on each individual requirements.*

### **1.3 Basic concept for quality**

*We, at Mikuni, are committed to the enhancement of quality assurance system and thoroughness of quality control in the steps of planning, development, design, procurement, sales, after-sales-service and deliver, and making effort to provide the product 100% satisfactory to each individual customer. In order to provide each individual customer with 100% satisfaction, product defect is not allowed. Even if there is only one product defect, customer using it is dissatisfied and 100% satisfaction is not provided.*

*The cooperation to quality assurance activities by supplier producing constituent parts is necessary in order to provide each individual customer with 100% satisfaction, because Mikuni's products are composed of many parts and most are produced by supplier. Therefore, we would like to request all suppliers to meet the quality assurance requirements defined in this Supplier Quality Assurance Procedure and certified International standard for quality assurance management system ISO9001 (Certified registration by a third-party certificationbody), with the ultimate objective of becoming certified automotive quality management system standardIATF16949. In addition, we will contact the supplier who does not apply the quality management system Certification request for an official exemption*

*You are kindly requested to fully understand Mikuni's basic concept for quality assurance and extend your utmost cooperation in this matter.*

### **1.4 Revisions**

*This Supplier Quality Assurance Procedure may be revised without prior notice. Mikuni will send revised edition when revised, please replace it with invalid edition. In addition, when instruction for disposal of invalid edition is given by Mikuni, please follow Mikuni's instruction.*

### **1.5 Contact desk for inquiry**

*If you have any inquiry, opinion or request for this Supplier Quality Assurance Procedure, please contact Mikuni Purchase Dept.*

**2. Applicable phases of quality assurance requirements :**

Level	Document preparation	Submission to Mikuni	Mikuni approval
1	Required	Required	Required
2	At our request	At our request	At our request
3	Required	Required	Any
4	Required	At our request	Any
5	At our request	At our request	Any

Activity	Submission	Format number	Level	Submit to	program	Parts	Normal	Regular	Mass	Close	production
					Decision	design	type	process	production	early-	Discontinua-
					Approval	Arrange	Completed	start	stage	tion	
3.1.1 Appointment and notification of responsible person	Notification of responsible person for quality	Form 1	3	Purchasing Dept.							
3.1.2 Competence of personnel	-	-	-	-							
3.1.3 Control of Sub-suppliers	-	-	-	-							
3.1.4 Control measuring instruments	-	-	-	-							
3.1.5 Internal audit	-	-	-	-							
3.2.1 Control of quality documents	-	-	-	-							
3.2.2 Control of quality records	-	-	-	-							
3.3.1 Control of special characteristics	-	-	-	-							
3.3.2 Control of process capability	-	-	-	-							
3.4.1 Kick off meeting	-	-	-	-							
3.4.2 Preparation and management of APQP	APQP	Form 15	4	Direct from Mikuni							
3.4.3 Multidisciplinary approach	-	-	-	-							
3.4.4 Creation of Development History Log.	Development History Log.	Arbitrary format	4	Direct from Mikuni							
3.5.1 Consideration of design concept	-	-	-	-							
3.5.2 Design FMEA	Design FMEA sheet	Form 2	2	Direct from Mikuni							
3.5.3 Nonconformity prevention by design	-	-	-	-							
3.5.4 Design review	-	-	-	-							
3.5.5 Reliability test	-	-	-	-							
3.6.1 Planning of Floor layout	Floor layout	Arbitrary format	4	-							
3.6.2 Process FMEA	Process FMEA sheet	Form 3	4	Direct from Mikuni							
3.7.1 Decision of packaging specification	Packaging specification	Form 4	1	Purchasing Dept.							
3.7.2 Development of Control plan	Control Plan	Form 5	1	Quality control Dept.							
3.7.3 Creation of Parts Inspection Standards	Parts Inspection Standard Sheet	Forms 6-1, 6-2	1	Quality control Dept.							
3.7.4 Preparation of work instructions	-	-	-	-							
3.7.5 Pre-production	-	-	-	-							
3.7.6 Imprementation of transition to mass production	Free form	Arbitrary format	4	Direct from Mikuni							
3.7.7 Submission of Parts Inspection Report	Parts Inspection Report Tag for First	Forms 7-1, 7-2 Form 8	1	Delivery parts attached							
3.7.8 Submission of Parts Submission Warrant (PSW)	Parts Submission Warrant(PSW)	Form 9	1	Quality control Dept.							
3.8.1 Initiation control	Free form	Arbitrary format	4	Direct from Mikuni							
3.8.2 Securing of traceability	-	-	-	-							
3.8.3 Proposal for design change	Design Change Request	Form 10	1	Purchasing Dept.							
3.8.4 Control of process change	Process Change Request First item	Form 11 Form 8	1	Purchasing Dept.							
3.8.5 Control of variation point	-	-	-	-							
3.8.6 Control of non-conforming parts	-	-	-	-							
3.8.7 Deviation request	Deviation request Identification tag for deviation	Form 12 Form 13	1	Purchasing Dept.							
3.8.8. Reaction for nonconformity of parts already deliverd	Corrective action report	Form 14 or our designated form	2	Purchasing Dept.							
3.8.9 Change freeze period	-	-	-	-							

... Time of application. (including follow-up)

## Quality assurance requirements

### 2.1 General requirements

#### 2.1.1 Appointment and notification of responsible person

##### (1) Objective

The objective is to clarify where responsibility for quality assurance, sales and delivery as well as contact person from Mikuni.

##### (2) Application

This section shall be applied to business with Mikuni.

##### (3) Requirements

Appoint a person satisfying appointment criteria defined in the table below.

Classification	Appointment criteria
General Manager for Quality Assurance	Has received delegation of responsibility and authority related to quality assurance from top management (In principle position above general manager's class .)
Quality Manager	Capable of practical management related to quality assurance (In principle, title above section manager class)
General Manager for Sales	Has received delegation of responsibility and authority related to sales and delivery from top management (Position above section manager's class in principle)
Sales Manager	Capable of practical management related to sales and delivery (In principle, title above section manager class)
Emergency Contact	Capable of accepting emergency contacts including at night and holiday.

- If there are multiple facilities that produce parts ordered from Mikuni, appoint a quality manager for each facility.
- The quality manager should be able to receive contact in the event of an emergency including night and holidays (If the manager is different between normal and emergency, he / she will be appointed individually).

##### (4) Notification to Mikuni

Items	Description
Submission	Notification of responsible person for quality
Subject	All suppliers
Notification form	Form1 (Fill in the items prepared without omission)
Notification date	1 <sup>st</sup> notification...Within 1 month from concluding Basic Contract Document or 5 days before first product delivery, whichever comes earlier Change of notification contents...Within 1 month from the date that change is made
Notify to	Purchase Dept.
Original/copy	Original

#### 2.1.2 PPAP Submission :

The purpose of Production Part Approval Process (PPAP) is to:

- Ensure that a supplier can meet the manufacturability and quality requirements of the parts supplied to the Mikuni India Private Limited.
- Provide evidence that the Mikuni India's engineering design record and specification requirements are clearly understood and fulfilled by the supplier
- Demonstrate that the established manufacturing process has the potential to produce the part that consistently meets all requirements during the actual production run at the quoted production rate of the manufacturing process.

Suppliers are required to obtain PPAP approval from Mikuni India whenever a new or modified component is introduced to production, or the manufacturing process is changed. Obtaining approval requires the supplier to provide sample parts and documentary evidence showing that:<sup>[2]</sup>

1. Mikuni India's requirements have been understood;
2. The product supplied meets those requirements;
3. The process (including sub suppliers) is capable of producing conforming product;
4. The production control plan and quality management system will prevent non-conforming product reaching Mikuni India or compromising the safety and reliability of finished End product.

PPAP may be required for all components and materials incorporated in the finished product and may also be required if components are processed by external sub-contractors.

PPAP requirements are typically distinguished by level as follows:

- Level 1 – Part Submission Warrant (PSW) only submitted to the customer.
- Level 2 – PSW with product samples and limited supporting data.
- Level 3 – PSW with product samples and complete supporting data.
- Level 4 – PSW and other requirements as defined by the customer.
- Level 5 – PSW with product samples and complete supporting data available for review at the supplier's manufacturing location. Complete documentation

Mikuni India private limited follows and approves the level # 3 of PPAP, REFER **FORM 16 MID PPAP Requirement PSW REFER Appendix9 (MID-Q06-002)**

Product PPAP shall be taken from a significant production run. This significant production run shall be from one hour to eight hours of production and with the specific production quantity of minimum 300 consecutive parts, unless specified by authorized MID representative.

### **2.1.3 Competence of personnel :**

#### **(1) Objective**

The objective is to ensure that the work affecting quality shall be performed by personnel who are competent.

#### **(2) Application**

This section shall be applied to the work affecting quality of parts ordered by Mikuni.

#### **(3) Requirements**

- a. After clarifying competence required for personnel engaged in the operations that affect the performance, quality and effectiveness of the quality management system, let the competent personnel to perform the work. In addition, make the personnel understand about the impact that nonconformity with quality requirements requirements have on customers (internal, external, end users).
- b. Evaluate periodically the competence of personnel on basis of education, training, skills and experience.
- c. Define, Identify, plan and implement the education and training needs to acquire the necessary competence and the competence to be achieved.
- d. Provide on-the-job training (OJT) to personnel (include contractor, agency personnel) for new or modified work that affect quality.
- e. Maintain the records about the training implemented.
- f. Qualification is regularly conducted for personnel engaged in special processes and operations that affect special characteristics.

### **2.1.4 Control of Sub-suppliers**

#### **(1) Objective**

The objective is that when raw material, constituent parts, and/or all or part of manufacturing process are subcontracted or utilize sub-supplier appropriate controls are applied to subcontracting parts and

*manufacturing process and that parts subcontracted ensure meeting requirements.*

**(2) Application**

*This section shall be applied to suppliers who utilize sub-supplier to manufacture the parts ordered by Mikuni.*

**(3) Requirements**

- a. *Evaluate and select sub-supplier on basis of capability of supplying goods conforming to requirements.*
- b. *Ensure that items from sub-supplier and manufacturing processes meet Mikuni's quality assurance requirements. Apply equally this to all goods and manufacturing processes subcontracted further by sub-supplier*
- c. *Have the process to assure quality of goods from sub-supplier .*
- d. *Include the following to controls applied for sub-supplier r.*
  - *Transmit Mikuni's quality assurance requirements in writing and make a sub-supplier apply it,*
  - *Clarify and transmit the purchasing information of subcontracting goods that is indispensable for ordering,*
  - *Perform the quality audit periodically and confirm the quality assurance system and status of process control (It may be omitted if subcontracting goods are standard items). In addition, make a sub-supplier take the appropriate measures for problems or issues that became apparent by audit.*
- e. *Monitor continuously the performance of sub-supplier quality and delivery.*
- f. *Maintain the records about result of quality audit for supplier (Including measures taken for detected problems and issues) and monitored performance of supplier.*

**2.1.5 Control of measuring instruments**

**(1) Objective**

*The objective is to maintain the trueness and function of measuring instruments (Including gauges and test machines) and ensure the reliability of inspection and test.*

**Application**

*This section shall be applied to measuring instruments used for quality assurance of parts ordered by Mikuni.*

**(2) Requirements**

- a. *Use the measuring instruments having the scale interval that tolerance end digit of measured item is readable (It is desirable to be readable to digit of one-tenth of tolerance end digit) and being calibrated before starting use and periodically. Define the calibration interval and calibration standard in advance.*
- b. *Perform the calibration using the standard traceable to international or national standards. Record the standard used for calibration if no such standard exists.*
- c. *Mark the expiry date or information for referring it on measuring instruments, and handle, retain and protect the measurement instrument in appropriate manner to maintain their trueness and function.*
- d. *Measure again the parts that were measured by measuring instrument deviating from calibration standard, by measuring instrument that conforms to calibration standard, and evaluate validity of past measurement result and magnitude of effect, when it is found that measuring instrument deviates from calibration standard. Take the appropriate measures including recall of parts already delivered to Mikuni to all parts affected (If the suspect part has already been delivered to Mikuni or suspected of being delivered to Mikuni, promptly contact purchasing department for take directions)*



- e. *Maintain the records about calibration data, data after adjustment, repair history, evaluation of measurement result before finding deviation from calibration standard, and measures taken for parts affected by deviation from calibration standard.*

### **2.1.6 Internal Audit :**

#### **(1) Objective**

*The objective is to self-audit own quality assurance activities from viewpoint of whether it conforms to requirements applied and to enhance the effectiveness of quality assurance activities through improvement of problems and issues that became apparent.*

#### **(2) Application**

*This section shall be applied to parts ordered by Mikuni and related quality assurance activities.*

#### **(3) Requirements**

- a. *Perform the internal audit yourself for own quality assurance activities. And confirm that the following items are met.*
  - *Conform to your own requirements for its quality management system*
- b. *Perform the following items for internal audit.*
  - *Plan, establish, implement and maintain an audit program that including audit frequency methods, responsibilities, planning requirements and reporting.*
  - *The scope of the audit includes all activities required to guarantee the quality of parts ordered from Mikuni.*
  - *Select appropriate auditors and conduct audits to ensure the objectivity and impartiality of the audit process.*
  - *Ensure that the results of the audits are reported to relevant management.*
  - *Take appropriate correction and corrective actions to the problems and issues that have been detected without undue delay.*
  - *Retain records as evidence of the implementation of the audit program and the results of the audits (including actions taken on detected problems and issues).*
- c. *Documented internal audit process that includes the development and implementation of an internal audit program that covers the entire quality management system, including quality management system audits, manufacturing process audits and product audits.*
- d. *The audit program prioritizes based upon risks (including changes and previous audit results), internal and external performance trends and criticality of the process.*
- e. *Review and where appropriate adjusted audit frequency based on occurrence of process changes, internal and external nonconformities, and complaints.*
- f. *Program effectiveness shall be reviewed as a part of management review.*
- g. *In order to verify all quality management system processes according to an annual program using the process approach to verify compliance with this Supplier Quality Assurance Procedure and the automotive quality management system standard IATF 16949.*
- h. *Manufacturing process audits include the following.*
  - *Auditing of all manufacturing processes (cover all mikuni products) once a year with the aim of determining manufacturing process effectiveness and efficiency.*
  - *Audit all shifts, including appropriate sampling of shift takeovers.*

*Auditing the suitability of operating a manufacturing process as it is used to control the process such as Process FMEA ,Control Plan and work instructions*

- *Audit whether quality improvement activities implemented are effective.*
- i. Product audits should include the following :*
  - *Audit to be conducted once a year and cover all mikuni products.*
  - *Audit whether parts produced are conforming to requirements specified in part drawing, assembly drawing and engineering standard issued by Mikuni.*
  - *Audit whether the packaging and labeling conform to the packaging specifications.*  
*Maintain the records about result of audit (Including measures taken for detected problems and issues).*
- j. Layout Inspection : Layout inspection shall be done once in a year for all mikuni parts.*

### **3.2 Control of documents and records**

#### **3.2.1 Control of quality documents**

##### **(1) Objective**

*The objective is to control appropriately the documents used for managing quality assurance activities or assuring quality and make available effectively.*

##### **(2) Application**

*This section shall be applied to documents related to quality assurance activities for parts ordered by Mikuni.*

##### **(3) Requirements**

- a. Prior to issuance of the document, authorized person shall check document if it is appropriate or not in addition, review the adequacy and appropriateness of the issued documents, update and re-approve as necessary. Clarify the identification of revision so that which current edition is can be identified, when revising a document.*
- b. Make available appropriate edition of document on when needed at where needed.*
- c. Remove or clearly identify a document that became invalid (abolition or old edition) so as not to be used erroneously. In addition, retain the profitable documents from viewpoint of product liability defense continuously thereafter even if it became invalid.*
- d. Complete the review of contents within 2 working weeks from receiving when received a design document (e.g., part drawing, assembly drawing , engineering standard, etc.) issued by Mikuni. In addition, maintain the records about implementation date of change in production when design document is changed.*

#### **3.2.2 Control of quality records**

##### **(1) Objective**

*The objective is to prepare appropriately the records to prove that quality assurance is suitable and make it available as evidence of quality assurance when needed.*

##### **(2) Application**

*This section shall be applied to records related to quality assurance activities for parts ordered by Mikuni.*

##### **(3) Requirements**

- a. Make a quality record so that it is legible and appropriately contains the identification information for identifying goods or activities subject to record, and retain under environment that can prevent deterioration and damage and is suitable to protect for a long term so that it is retrievable (Medium of record is acceptable in anything such as hard copy or electromagnetically medium, etc.).*
- b. Determine the retention period of quality record so that it meets the period defined in the table below (Apply the longest retention period among applicable classification when record is applicable for more than 2 of the classifications in the table. In addition, follow that instruction accordingly when special*

Classification	Retention period	Remarks
Vital records to prove that parts produced satisfy the requirements.	15 years	As well as a direct record for parts produced (e.g., inspection record), include an indirect record (e.g., monitor record of process parameter) if applicable.
Vital records for tracing manufacturing history and whereabouts of parts produced.	15 years	
Other records (as required by Mikuni)	15 years	

c. Submit according to Mikuni's request unless there is justifiable reason, when received the submission request of quality record from Mikuni.

### 3.3 Control of quality characteristics






#### 3.3.1 Control of special characteristics

(1) Objective

The objective is to minimize a risk of occurrence of physical injury, fire or deviation from regulation due to defect of part by taking special regime different from general characteristics.

(2) Application

This section shall be applied to special characteristics as specified in part drawing & assembly drawing issued by Mikuni.

Classification		Symbol	Description
Special characteristics	Critical safety characteristics	Safety	 Characteristic that might cause the failure having a possibility of resulting in physical injury by presence of a defect.
		Fire prevention	 Characteristic that might cause the failure having a possibility of resulting in fire by presence of a defect.
		Exhaust gas control	 Characteristic that may cause the deviation from regulation such as exhaust gas increase by presence of a defect.
	Critical quality characteristics		 Region that has particularly high contribution rate of flow rate accuracy among functional parts of carburetor (Called Important Control Point). This region shall be controlled by statistical method.
	Securement of quality	 Characteristic that might cause the critical quality nonconformities, nonconformities to lower commodity value remarkably, or nonconformities to deviate from regulation by presence of a defect, or characteristic specified by customer (other than critical safety characteristics (safety, fire prevention, exhaust gas control))	

(3) Requirements

a. Mark the symbol for special characteristics specified by Mikuni or supplier on applicable places of documents used for control process such as part drawing and assembly drawing. Design FMEA (See 3.5.2), Process FMEA (See 3.6.2), Control Plan (See 3.7.2), work instructions (See 3.7.4) and check sheet, and inform to personnel that it is critical characteristic and control competence.

b. The display of special characteristic symbols on documents used to control processes such as process FMEA, Control Plan, and Work Instruction, It displays and manages not only the characteristics indicated by the part drawing and assembly drawing, but also important process parameters for controlling the characteristics indicated by the part drawing and assembly drawing

c. Display the signboard indicating being process affecting special characteristics (Process for purpose of

*making or direct inspection of special characteristics) in process affecting special characteristics.*

- d. *Plan and implement the management of priorities commensurate with their importance for special characteristics. In addition, apply the controls required to achieve and maintain the requirement level of process capability (See 3.3.2).*

**3.3.2 Control of process capability**

(1) Objective

*The objective is to stabilize the quality level and performance level of Mikuni's products that incorporated the parts by controlling process capability and reducing its dispersion.*

(2) Application

*This section shall be applied to quality characteristics defined in part drawing and assembly drawing issued by Mikuni or alternative characteristics used to control them.*

Requirements

- (3) *Secure the process capability of requirement level defined in the table below. Take additional actions to assure 100% of quality characteristics applicable, if process capability is insufficient*

Classification		Symbol	Requirement level	Remarks
Critical safety characteristics	Safety		Index ≥ 1.67	Adopt more reliable controls to prevent the outflow of parts with outside tolerance (automatic measurement by automatic control system, multiple error detection in subsequent works, etc.) if additional measures for 100% assurance due to insufficient process capability are required.
	Fire prevention			
	Exhaust gas control			
Critical quality characteristics	Securement of quality		Index ≥ 1.67	Adopt more reliable controls to prevent the outflow of parts with outside tolerance (automatic measurement by automatic control system, multiple error detection in subsequent works, etc.) if additional measures for 100% assurance due to insufficient process capability are required.
	General characteristics		Index ≥ 1.33	

$C_p = \frac{(USL - LSL)}{6(\bar{R}/d_2)}$	
$C_{pk} = \frac{(USL - \bar{X})}{3(\bar{R}/d_2)}$	$\text{or } \frac{(\bar{X} - LSL)}{3(\bar{R}/d_2)}$
	<p><i>In case of bilateral tolerances ... Minimum value</i>  <i>In case of unilateral tolerances ... Either of computable</i></p>
$P_p = \frac{(USL - LSL)}{6s}$	
$P_{pk} = \frac{(USL - \bar{X})}{3s}$	$\text{or } \frac{(\bar{X} - LSL)}{3s}$
	<p><i>In case of bilateral tolerances ... Minimum value</i>  <i>In case of unilateral tolerances ... Either of computable</i></p>

$C_p$	Index to evaluate whether process has capability to meet specification.
$C_{pk}$	Index adding bias to $C_p$ (location of distribution).
$P_p$	Index to evaluate whether the outputs from process are meeting specification.
$P_{pk}$	Index adding bias to $P_p$ (location of distribution).
$USL$	Upper specification limit.
$LSL$	Lower specification limit.
$\bar{X}$	Average value of $X$ (mean of subgroup).
$\bar{R}$	Average value of $R$ (difference of Max. and Min. values in subgroup) of all subgroups.
$d_2$	Constant for obtaining estimate of standard deviation (See the table on right).
$s$	Standard deviation.
$n$	Number of observed value per subgroup.

$n$	$d_2$	$n$	$d_2$
1	----	16	3.532
2	1.128	17	3.588
3	1.693	18	3.640
4	2.059	19	3.689
5	2.326	20	3.735
6	2.534	21	3.778
7	2.704	22	3.819
8	2.847	23	3.858
9	2.970	24	3.895
10	3.078	25	3.931
11	3.173		
12	3.258		
13	3.336		
14	3.407		
15	3.472		

- Calculate and evaluate the process capability monthly not only in prior production and initial stage of production (See 3.7.5 and 3.8.1) but even after the start of production.
- Plan and implement the process improvement to reduce the dispersion if possible (Implement similarly even after index reaches requirement level).

**Measurement System Analysis** : MSA plan to be prepared annually for all inspection & measurement system identified in control plan. Record of analysis shall be maintained.

NOTE : Prioritization of MSA studies should focus on Critical or Special Product / Process characteristics.

### 3.4 Project management

#### 3.4.1 Kick-off meeting

##### (1) Objective

The objective is to share specific product information including function and duty of part and master schedule until production with Mikuni, and endeavor for securing performance and function of Mikuni's new product.

##### (2) Application

This section shall be applied when received notice of convocation from Mikuni (Suppliers who produce important part to secure the performance or function of Mikuni's new product are convened).

##### (3) Requirements

- Make a person having responsibility and authority for subject parts attend kick-off meeting and receive the explanation of product information (concept, function and quality requirements of product developed by Mikuni) and master schedule until production.
- Grasp the function and duty of part level, and hear the detail information from Mikuni, if necessary.
- Offer actively the proposal or request to Mikuni as a professional manufacturer for subject part.
- Transmit the obtained information in a kick-off meeting into the company, reflect to Advanced Product Quality Plan manage it and followup.

#### 3.4.2 Preparation and management of Advanced Product Quality Plan

##### (1) Objective

The objective is to clarify the steps required during the period from initial stage of development to the start of production, complete them precisely and timely and realize the smooth production setup, for producing the parts meeting requirements stably.

##### (2) Application

This section shall be applied to parts ordered by Mikuni.

##### (3) Requirements

- a. *Formulate Advanced Product Quality Plan (Also called APQP) including overall schedule plan up to project completion on basis of Mikuni's master schedule. In addition, formulate detailed schedule to supplement the above if necessary.*
- b. *Confirm the progress of Advanced Product Quality Plan periodically, and fill it out in form that a plan and results can be compared. Update it appropriately when it is necessary to change a plan.*
- c. *Include the activities that become the milestones of project into Advanced Product Quality Plan appropriately. Decide whether it may advance to next step through confirming the following by executive having responsibility and authority, at milestone of project.*
  - *Progress status of Advanced Product Quality Plan,*
  - *Performance for objectives of quality, cost and timing,*
  - *Reaction status for problems and issues that became apparent.*
- d. *Look back on project and clarify the issues and learning that should be taken over to next project when project is terminated.*

(4) *Submission to Mikuni*

<i>Items</i>	<i>Description</i>
<i>Subject</i>	<i>APQP Timing Plan</i>
<i>Submission form</i>	<i>Not specified</i>
<i>Submission date</i>	<i>Parts that kick-off meeting (See 3.4.1) was held...Within 30 days from kick-off meeting Parts specified by Mikuni...Specified date</i>
<i>Submit to</i>	<i>Purchase Dept.</i>
<i>Original/copy</i>	<i>Copy</i>

### **3.4.3 Multidisciplinary approach**

(1) *Objective*

*The objective is that representatives of functions related to project cooperate multidisciplinary, orchestrate the knowledge and experiences and reflect into part or process.*

(2) *Application*

*This section shall be applied to parts ordered by Mikuni.*

(3) *Requirements*

- a. *Implement the following activities by multidisciplinary approach.*
  - Agreement of Inspection /Testing FORM 15. ELV report to be submitted on yearly basis.*
  - *Preparation and review of Advanced Product Quality Plan (See 3.4.2),*
  - *Identifying special characteristics (See 3.3.1) and monitoring during project period,*
  - *Implementation and review of FMEA (See 3.5.2 and 3.6.2) including measures taken to reduce a risk,*
  - *Planning for plant, facility and equipment,*
  - *Development and review of Control Plan (See 3.7.2),*
  - *Pre-production (See 3.7.5),*
  - *Initiation control (See 3.8.1).*
- b. *Include design, production engineering, quality, manufacturing, purchase, sales and other appropriate personnel into multidisciplinary approach.*

### **3.4.4 Creation of Development History Log :**

(1) *Objective*

*The objective is to ensure that problems and issues that became apparent before the start of production are solved without omission, and accumulate their histories and utilize effectively for future activities.*

(2) *Application*

*This section shall be applied to parts ordered by Mikuni.*

(3) *Requirements*

- a. *Fill in development resume (List of problems identified) with problems and issues that became*

*apparent from the order to the start of production without omission.*

- b. Solve all problems and issues that became apparent until the start of production. Confirm individually that actual measures taken were performed as intended, on basis of objective fact.*
- c. Maintain the records about measures taken to solve the problems or issues and confirmation result after measures completion.*

<i>Items</i>	<i>Description</i>
<i>Subject</i>	<i>Development History Log</i>
<i>Submission form</i>	<i>Not specified</i>
<i>Submission date</i>	<i>To be specified each time by Mikuni</i>
<i>Submit to</i>	<i>Purchase</i>
<i>Original/copy</i>	<i>Copy</i>

### **3.5 Part design and development**

#### **3.5.1 Consideration of design concept**

##### **(1) Objective**

*The objective is to grasp Mikuni's design specification and quality requirements and ensure that parts designed meet Mikuni's requirements.*

##### **(2) Application**

*This section shall be applied to parts designed by supplier on basis of Mikuni's design requirements.*

##### **(3) Requirements**

- a. Determine the design specification and quality requirements including usage environment and the uses of parts at first stage of design and review the contents.*
- b. Determine the design concept including the following as meeting design specification and quality requirements. Document these to avoid the omission, ambiguity and contradiction.*
  - Design objectives (Including objectives related to product life, reliability, durability, maintainability, timing and cost),*
  - Design concepts to support the design objectives,*
  - Sketch of part,*
  - Special characteristics (See 3.3.1) and major characteristics,*
  - Schematic part configuration,*
  - Difference from conventional parts,*
  - Material used and activity plan, when using materials containing regulated substances.*
- c. Implement the review of design concept when it is known, in the event that design specification and quality requirements clarified are changed later.*

#### **3.5.2 Design FMEA (Failure Mode and Effects Analysis)**

##### **(1) Objective**

*The objective is to recognize conceivable failure mode of design and its effect, and clarify measures taken to eliminate the opportunities of occurring failure or reduce it.*

##### **(2) Application**

*This section shall be applied to parts designed by supplier on basis of Mikuni's design requirements.*

##### **(3) Requirements**

- a. Start Design FMEA from initial stage of design, and, thereafter review the content through design process whenever design change occurs or new information (nonconformity information, etc.) is input. In addition, method to share Design FMEA may be adopted for similar parts.*
- b. Include all elements that constitute the part such as raw material and child part, into Design FMEA.*

- c. Refer to FMEA manual issued by AIAG (Automotive Industry Action Group) about concrete implementation procedure.
- a. Prioritize preventive treatment over the detection of recommended treatment to lower the score. This recommended action will consider applying the ranks in the following order.

- Severity
- Occurrence
- Detection
- RPN (more than 100)

Items	Description
Subject	Design FMEA Sheet
Submission form	Apendix 2 , FORM 2
Submission date	Specified date
Submit to	Purchase
Original/copy	Copy

Reference 1 (Evaluation criteria of severity /Design FMEA)

Effect	Criteria : Severity of effect on product (Customer effect)	Rank
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	10
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9
Loss or Degradation of Primary Function	Loss of primary function (Vehicle inoperable, does not affect safe vehicle operation).	8
	Degradation of primary function (Vehicle operable, but at reduced level of performance).	7
Loss or Degradation of Secondary Function	Loss of secondary function (Vehicle operable, but comfort/convenience functions inoperable).	6
	Degradation of secondary function (Vehicle operable, but comfort/convenience functions at reduced level of performance).	5
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (>75%).	4
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%).	3
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%).	2
No effect	No discernible effect.	1



## Reference 2 (Evaluation criteria of occurrence /Design FMEA)

Likelihood of failure	Criteria : Occurrence of cause - DFMEA (Design life/reliability of item/vehicle)	Criteria : Occurrence of cause - DFMEA (Incidents per items/vehicles)	Rank
Very high	New technology/new design with no history.	$\geq 100$ per thousand $\geq 1$ in 10	10
High	Failure is inevitable with new design, new application, or change in duty cycle/operating conditions.	50 per thousand 1 in 20	9
	Failure is likely with new design, new application, or change in duty cycle/operating conditions.	20 per thousand 1 in 50	8
	Failure is uncertain with new design, new application, or change in duty cycle/operating conditions.	10 per thousand 1 in 100	7
Moderate	Frequent failures associated with similar designs or in design simulation and testing.	2 per thousand 1 in 500	6
	Occasional failures associated with similar designs or in design simulation and testing.	.5 per thousand 1 in 2,000	5
	Isolated failures associated with similar designs or in design simulation and testing.	.1 per thousand 1 in 10,000	4
Low	Only isolated failures associated with almost identical design or in design simulation and testing.	.01 per thousand 1 in 100,000	3
	No observed failures associated with almost identical design or in design simulation and testing.	$\leq .001$ per thousand 1 in 1,000,000	2
Very low	Failure is eliminated through preventive control.	Failure is eliminated through preventive control.	1

## Reference 3 (Evaluation criteria of detection /Design FMEA)

Detection	Criteria : Likelihood of detection by design control	Rank	Likelihood of detection
No detection opportunity	No current design control ; Cannot detect or is not analyzed.	10	Almost impossible
Not likely to detect at any stage	Design analysis/detection controls have a weak detection capability. Virtual Analysis (e.g., CAE, FEA, etc.) is not correlated to expected actual operating conditions.	9	Very remote
Post design freeze and prior to launch	Product verification/validation after design freeze and prior to launch with pass/fail testing (Subsystem or system testing with acceptance criteria such as ride and handling, shipping evaluation, etc.).	8	Remote
	Product verification/validation after design freeze and prior to launch with test to failure testing (Subsystem or system testing until failure occurs, testing of system interactions, etc.).	7	Very low
	Product verification/validation after design freeze and prior to launch with degradation testing (Subsystem or system testing after durability test, e.g., function check).	6	Low
Prior to design freeze	Product validation (Reliability testing, development or validation tests) prior to design freeze using pass/fail testing (e.g., acceptance criteria for performance, function checks, etc.).	5	Moderate
	Product validation (Reliability testing, development or validation tests) prior to design freeze using test to failure (e.g., until leaks, yields, cracks, etc.).	4	Moderately high
	Product validation (Reliability testing, development or validation tests) prior to design freeze using degradation testing (e.g., data trends, before/after values, etc.).	3	High
Virtual analysis – correlated	Design analysis/detection controls have a strong detection capability. Virtual analysis (e.g., CAE, FEA, etc.) is highly correlated with actual or expected operating conditions prior to design freeze.	2	Very high
Detection not applicable ; failure prevention	Failure cause or failure mode cannot occur because it is fully prevented through design solutions (e.g., proven design standard, best practice or common material, etc.).	1	Almost certain

**3.5.3 Nonconformity prevention by design**

## (1) Objective

The objective is to prevent the defect by incorporating design countermeasures for design nonconformities experienced in the past and manufacturing nonconformities that are avoidable by design.

## (2) Application

This section shall be applied to parts designed by supplier on basis of Mikuni's design requirements.

## (3) Requirements

- a. Consider the sufficient design countermeasures to prevent the occurrence of design nonconformities experienced in the past and manufacturing nonconformities foreseeable in design stage, and incorporate them into design.
- b. Compile a database of information related to design nonconformities experienced in the past and input it into Design FMEA (See 3.5.2) and design review (See 3.5.4).
- c. Maintain the records about design countermeasures taken to prevent the nonconformity.

### **3.5.4 Design review**

#### **(1) Objective**

*The objective is to evaluate whether result of design can meet the requirements, to clarify the problems further and to determine necessary measures.*

#### **(2) Application**

*This section shall be applied to parts designed by supplier on basis of Mikuni's design requirements.*

#### **(3) Requirements**

- a. *Perform the design review in accordance with Advanced Product Quality Plan (See 3.4.2) planned, at suitable design stage.*
- b. *Include the representative of function concerned with subject design into participants.*
- c. *Include the following in design review, and agree its conclusion upon among participants.*
  - *Design specification,*
  - *Result of Design FMEA (See 3.5.2),*
  - *Progress and result of reliability test (See 3.5.5),*
  - *Status of incorporating design countermeasures for nonconformities experienced in the past.*
- d. *Perform the joint design review with function concerned of Mikuni at the timing required by Mikuni if required by Mikuni. In this case, complete the design review in supplier alone in advance.*
- e. *Maintain the records about result of design review (Including countermeasures required for problems and issues detected).*

### **3.5.5 Reliability test**

#### **(1) Objective**

*The objective is to ensure that parts obtained as a result of design and development is suitable and adequate for Mikuni's design specification and quality requirements.*

#### **(2) Application**

*This section shall be applied to parts designed by supplier on basis of Mikuni's design requirements.*

#### **(3) Requirements**

- a. *Plan the reliability tests required to confirm whether parts satisfy the design specification and quality requirements so that all tests are completed before parts shipment is started, and manage the progress.*
- b. *Include appropriately the reliability test items that necessity was clarified through Design FMEA (See 3.5.2).*
- c. *Adjust the schedule and allotment with Mikuni Engineering Dept., if reliability test must be performed under condition incorporated in Mikuni's product.*
- d. *Perform the reliability tests by using all-tooling parts (trial parts produced using mold, equipment, and jig and tool same as production). Clarify the problems (issues of concern) and measures by not using all-tooling parts if all-tooling parts are not used.*
- e. *Maintain the records about result of reliability test (Including measures taken based on test result).*

## **3.6 Process design**

### **3.6.1 Planning of floor layout**

#### **(1) Objective**

*The objective is to determine optimal floor layout to supply the parts meeting requirements stably.*

#### **(2) Application**

*This section shall be applied to parts ordered by Mikuni.*

#### **(3) Requirements**

- a. *Clarify the equipment arrangement, material flow (Including stagnation point), inspection point, isolation areas for nonconforming parts and interim repair stations in planning of floor layout and document its result as floor layout diagram. In addition, method to share the floor layout diagram may be adopted for similar parts that are produced in same manufacturing line.*

- b. *Include all processes from acceptance to delivery into floor layout diagram.*
- c. *Consider the following in planning of floor layout.*
  - *Effective use of floor space,*
  - *Flow of a balanced smooth material,*
  - *Mixing unintended materials.*
- d. *The floor layout diagram is used as input information to process FMEA.*

(4) *Submission to Mikuni*

<i>Items</i>	<i>Description</i>
<i>Subject</i>	<i>Floor layout diagram</i>
<i>Submission form</i>	<i>Appendix 3 (MID-Q06-002) , FORM 3</i>
<i>Submission date</i>	<i>Specified date</i>
<i>Submit to</i>	<i>Purchase</i>
<i>Original/copy</i>	<i>Copy</i>

**3.6.2 Process FMEA (Failure Mode and Effects Analysis)**(1) *Objective*

*The objective is to recognize conceivable failure mode of process and its effect, and clarify the measures taken to eliminate the opportunities of occurring nonconformity or detect it.*

(2) *Application*

*This section shall be applied to parts ordered by Mikuni.*

(3) *Requirements*

- a. *Start Process FMEA from initial stage of process design, and, thereafter review content through process design process whenever design change or process change occurs or new information (nonconformity information, etc.) is input. In addition, method to share Process FMEA may be adopted for similar parts that are produced in same manufacturing line.*
  - b. *Include all processes from in-plant receiving to delivery that may affect the production of parts such as shipping, receiving, transferring materials storage, conveyor transport, and labeling into Process FMEA.*
  - c. *Refer to FMEA latest manual issued by AIAG (Automotive Industry Action Group) about concrete implementation procedure.*
  - d. *Use Design FMEA (See 3.5.2), (when designed by supplier or provided by Mikuni), part drawing, assembly drawing, process flow diagrams), floor layout diagram (See 3.6.1) and information related to nonconformities experienced in the past etc, as information source for implementing Process FMEA.*
- (4) *Consider and create the recommended measures to reduce the rank when applicable to following order. Apply the error proofing method (POKAYOKE) as these recommended measures if feasible.*
- a. *Measures to reduce the Occurrence or Detection rank for items with high Severity rank (9 or more).*
  - b. *Measures to reduce the Occurrence rank for items with high Occurrence rank (3 and more)*
  - c. *Measures to reduce the Occurrence or Detection rank for items with high Occurrence or Detection rank (9 or more).*
  - d. *Measures to reduce the Occurrence or Detection rank for items with high R.P.N. (Risk Priority Number) (100 or more).*
- (5) *Ensure that the recommended actions planned in the process FMEA are addressed in the actual process.*

(6) *Submission to Mikuni*

<i>Items</i>	<i>Description</i>
<i>Subject</i>	<i>Process FMEA Sheet</i>
<i>Submission form</i>	<i>Appendix 3 (MID-Q06-002) Form 3 (Other format is acceptable if all items prepared are contained)</i>
<i>Submission date</i>	<i>Specified date</i>

Submit to	Purchase
Original/copy	Copy

## Reference 4 (Evaluation criteria of severity /Process FMEA)

Effect	Criteria : Severity of customer effect	Rank	Effect	Criteria : Severity of production effect
Failure to meet safety and/or regulatory requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	10	Failure to meet safety and/or regulatory requirements	May endanger operator (Machine or assembly) without warning.
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9		May endanger operator (Machine or assembly) with warning.
Loss or degradation of primary function	Loss of primary function (Vehicle inoperable, does not affect safe vehicle operation).	8	Major disruption	100% of product may have to be scrapped. Line shutdown or stop ship.
	Degradation of primary function (Vehicle operable, but at reduced level of performance).	7	Significant disruption	A portion of the production run may have to be scrapped. Deviation from primary process including decreased line speed or added manpower.
Loss or degradation of secondary function	Loss of secondary function (Vehicle operable, but comfort/convenience functions inoperable).	6	Moderate disruption	100% of production run may have to be reworked off line and accepted.
	Degradation of secondary function (Vehicle operable, but comfort/convenience functions at reduced level of performance).	5		A portion of the production run may have to be reworked off line and accepted.
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (>75%).	4	Moderate disruption	100% of production run may have to be reworked in station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%).	3		A portion of the production run may have to be reworked in-station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (< 25%).	2	Minor disruption	Slight inconvenience to process, operation, or operator.
No effect	No discernible effect.	1	No effect	No discernible effect.

## Reference 5 (Evaluation criteria of occurrence / Process FMEA)

<i>Likelihood of occurrence</i>	<i>Criteria : Occurrence of cause - PFMEA (Incidents per items/vehicles)</i>	<i>Rank</i>
<i>Very high</i>	<i>≥100 per thousand ≥1 in 10</i>	<i>10</i>
<i>High</i>	<i>50 per thousand 1 in 20</i>	<i>9</i>
	<i>20 per thousand 1 in 50</i>	<i>8</i>
	<i>10 per thousand 1 in 100</i>	<i>7</i>
<i>Moderate</i>	<i>2 per thousand 1 in 500</i>	<i>6</i>
	<i>.5 per thousand 1 in 2,000</i>	<i>5</i>
	<i>.1 per thousand 1 in 10,000</i>	<i>4</i>
<i>Low</i>	<i>.01 per thousand 1 in 100,000</i>	<i>3</i>
	<i>≤.001 per thousand 1 in 1,000,000</i>	<i>2</i>
<i>Very low</i>	<i>Failure is eliminated through preventive control.</i>	<i>1</i>

*Reference 6 (Evaluation criteria of detection /Process FMEA)*

<i>Opportunity for detection</i>	<i>Criteria : Likelihood of detection by process control</i>	<i>Rank</i>	<i>Likelihood of detection</i>
<i>No detection opportunity</i>	<i>No current process control ; Cannot detect or is not analyzed.</i>	<i>10</i>	<i>Almost impossible</i>
<i>Not likely to detect at any stage</i>	<i>Failure Mode and/or Error (Cause) is not easily detected (e.g., random audits).</i>	<i>9</i>	<i>Very remote</i>
<i>Problem detection post processing</i>	<i>Failure Mode detection post-processing by operator through visual/tactile/audible means.</i>	<i>8</i>	<i>Remote</i>
<i>Problem detection at source</i>	<i>Failure Mode detection in-station by operator through visual/tactile/audible means or post-processing through use of attribute gauging (Go/no-go, manual torque check/clicker wrench, etc.).</i>	<i>7</i>	<i>Very low</i>
<i>Problem detection post processing</i>	<i>Failure Mode detection post-processing by operator through use of variable gauging or in-station by operator through use of attribute gauging (Go/no-go, manual torque check/clicker wrench, etc.).</i>	<i>6</i>	<i>Low</i>
<i>Problem detection at source</i>	<i>Failure Mode or Error (Cause) detection in-station by operator through use of variable gauging or by automated controls in-station that will detect discrepant part and notify operator (Light, buzzer, etc.). Gauging performed on setup and first piece check (For set-up causes only).</i>	<i>5</i>	<i>Moderate</i>
<i>Problem detection post processing</i>	<i>Failure Mode detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing.</i>	<i>4</i>	<i>Moderately high</i>
<i>Problem detection at source</i>	<i>Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing.</i>	<i>3</i>	<i>High</i>
<i>Error detection and/or problem prevention</i>	<i>Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made.</i>	<i>2</i>	<i>Very high</i>
<i>Detection not applicable ; error prevention</i>	<i>Error (Cause) prevention as a result of fixture design, machine design or part design. Discrepant parts cannot be made because item has been error-proofed by process/product design.</i>	<i>1</i>	<i>Almost certain</i>

**3.7 Production preparation****3.7.1 Decision of packaging specification****(1) Objective**

*The objective is to clarify the packaging specification that can protect the quality of parts delivered during storage and transportation and satisfy Mikuni's packaging requirementApplication*

*This section shall be applied to parts ordered by Mikuni.*

**(2) Requirements**

- a. Perform the packing that taking out the parts is easy and can protect the quality during storage and transportation, for parts delivered (Avoid the use of inner material and fastener that have a fear leading to damage, deterioration and contamination adhesion of parts).*
- b. Define clearly the packaging specification for each part number and apply always the same packaging specification when shipping.*
- c. Perform the trial for transportation and storage in advance when adopting new packaging specification with no experience in the past.*

- d. *Keep the weight of 15Kg or less per 1 packaging.*
- e. *Indicate the part number, order number, part name, quantity contained, designated delivery date and supplier name on each packaging when delivering the parts (Style of indication is acceptable in anything).*
- f. *Maintain cleanliness of packing material without impairing aesthetics.*

*(3) Submission to Mikuni*

<i>Items</i>	<i>Description</i>
<i>Subject</i>	<i>Parts using the packaging other than Mikuni's returnable container or plastic bag, and parts specified by Mikuni</i>
<i>Submission form</i>	<i>Appendix 4 (MID-Q06-002) , Form 4</i>
<i>Submission date</i>	<i>As per timeline</i>
<i>Submit to</i>	<i>Purchase Dept.</i>
<i>Original/copy</i>	<i>Original (The original is returned after Mikuni checked.)</i>

### **3.7.2 Development of Control Plan**

*(1) Objective*

*The objective is to clarify all process controls required from acceptance to delivery for producing the parts meeting requirements stably as ultimate objectives.*

*(2) Application*

*This section shall be applied to parts ordered by Mikuni.*

*(3) Requirements*

- a. *Include all processes from acceptance to delivery into Control Plan and define all controls applied to their processes. In addition, method to share Control Plan may be adopted for similar parts produced in same manufacturing line. However, clarify the target parts (such as attaching a target parts list).*
- b. *Prepare Control Plan for a prototype stage for every part ordered from Mikuni, and prepare them for production by Pre-Production stage.*
- c. *As information source to develop Control Plan, include appropriately Design FMEA (See 3.5.2), (if designed by supplier or provided by Mikuni), Process FMEA (See 3.6.2) and information of nonconformities experienced in the past and secure the consistency with other documents used for controlling process.*
- d. *Fill in the name and address of manufacturer who is in charge of process subcontracted if part or all of processes are subcontracted (Excluding process for standard part incorporated into parts delivered).*
- e. *Define concrete and practical criteria if sensory evaluation is used for controlling process.*
- f. *If any of the following occurs, review the Control Plan and update it as necessary. In addition, even if it does not occur, review it at least once a year.*
  - *If it is determined that the nonconforming product has been shipped to Mikuni.*
  - *If there is a change that affects the risk analysis, such as changes in parts, manufacturing process, measurement, distribution, supply source, production volume, or FMEA.*
  - *After nonconforming product is found by Mikuni and corrective action is taken.*



(4) *Submission to Mikuni*

<i>Items</i>	<i>Description</i>
<i>Subject</i>	<i>Control Plan</i>
<i>Submission form</i>	<i>Appendix 5 (MID-Q0-002) , Form 5</i>
<i>Submission date</i>	<i>As per timeline</i>
<i>Submit to</i>	<i>Quality Control Dept.</i>
<i>Original/copy</i>	<i>Original (The original is returned after Mikuni checked. / If subject part is ordered by multiple Mikuni's sites, submit a copy containing Mikuni's receipt stamp, to site after 2nd).</i>
<i>Others</i>	<i>When confidential information treated as trade secret (own know-how, etc.) is included in Control Plan, it may be submitted after painting out the applicable place if agreed with Mikuni Purchase Dept.</i>

**3.7.3 Preparation of Part Inspection Standard**(1) *Objective*

*The objective is to clarify the shipment criteria of part to ensure that quality of parts shipped is assured.*

(2) *Application*

*This section shall be applied to parts ordered by Mikuni.*

(3) *Requirements*

- a. *Define the inspection item, specification/criteria, sample size/frequency and inspection tool necessary to assure the quality of parts shipped into Part Inspection Standard. In addition, method to share Part Inspection Standard may be adopted for similar parts.*
- a. *As information source to prepare Part Inspection Standard, include appropriately Design FMEA (See 3.5.2), (if designed by supplier or provided by Mikuni), Process FMEA (See 3.6.2), Control Plan (See 3.7.2) and information of nonconformities experienced in the past and secure the consistency with other documents used for controlling process and prepare them by Pre-Production stage.*
- b. *Take up falling under any of following as inspection item (But characteristics obtaining agreement with Mikuni Quality dept. may be excluded from inspection item).*
  - *Special characteristics (See 3.3.1),*
  - *Quality characteristics applied to severer tolerance than general tolerance,*
  - *Quality characteristics related to “places used by Mikuni's customer (Specified by Mikuni)”,*
  - *Others, critical quality characteristics for functions required to part.*

(4) *Submission to Mikuni*

<i>Items</i>	<i>Description</i>
<i>Subject</i>	<i>Part Inspection Standard</i>
<i>Submission form</i>	<i>Form 6-1 or Form 6-2 (Fill in the items prepared without omission)</i>
<i>Submission date</i>	<i>As per timeline</i>
<i>Submit to</i>	<i>Quality Control Dept. &amp; Purchase</i>
<i>Original/copy</i>	<i>Original (The original is returned after Mikuni checked. / If subject part is ordered by multiple Mikuni's sites, submit a copy containing Mikuni's receipt stamp, to site after 2nd).</i>

Others	<i>If boundary sample or standard sample is required as a part of Part Inspection Standard, prepare 2 equivalents and submit them together with Part Inspection Standard (One of them is held by Mikuni).</i>
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### **3.7.4 Preparation of work instructions :**

*(1) Objective*

*The objective is to clarify the work procedure and important point, make the personnel understand enough and familiarize them, for producing the parts meeting requirements stably as ultimate objectives.*

*(2) Application*

*This section shall be applied to parts ordered by Mikuni.*

*(3) Requirements :*

- a. Prepare the work instructions that include appropriately the information required by personnel, for important process in terms of quality (procedure, check method, knack of work, important point, etc.).*
- b. As information source to prepare the work instructions, include appropriately Design FMEA (See 3.5.2), if designed by supplier or provided by Mikuni) Process FMEA (See 3.6.2), Control Plan (See 3.7.2) and information of nonconformities experienced in the past, and secure the consistency with other documents used for controlling process.*
- c. Work instructions should be prepared and provided in a language understood by the personnel involved in the work.*
- d. Work instruction also includes rules for personnel safety.*
- e. Make available the work instructions prepared, for person who needs, on when needed, at work station.*
- f. Make the personnel performing applicable work understand the contents defined in work instructions, and provide training to perform as defined.*
- g. Make the supervisor of manufacturing process confirm daily whether the work is performed as defined in work instructions.*

### **3.7.5 Pre-production**

*(1) Objective*

*The objective is to evaluate before the start of production whether parts meeting requirements can be produced stably by performing trial manufacture under same condition as production.*

*(2) Application*

*This section shall be applied to parts ordered by Mikuni. But application to parts having higher commonality with conventional part may be excluded.*

*(3) Requirements :*

- a. Perform under same condition as production and in appropriate lot size for deciding whether it may start production, in all processes from acceptance to packing (Including equipment, jig and tool, process flow, gauge, raw material, work method, equipment setting, control items, control method and operator).*

- b. *Include the following applicable into investigation during pre-production.*
  - *Development status of manufacturing process (If it is as per planned),*
  - *Appropriateness of Control Plan (See 3.7.2) and Part Inspection Standard (See 3.7.3),*
  - *Appropriateness of work instructions (See 3.7.4),*
  - *Process capability (See 3.3.2),*
  - *Reactions taken for nonconformities experienced in the past,*
  - *Occurrence status of quality nonconformity.*
- c. *Decide whether it may start production from viewpoint of whether it can produce stably the parts meeting requirement, based on results of pre-production.*
- d. *Maintain the records about result of pre-production (Including measures taken for detected problems and issues) and assessment for the start of production.*

### **3.7.6 Implementation of transition to production judgment**

#### **(1)Objective**

*The objective is to determine whether the parts produced by Pre-production have reached the level that can be put on the market (deliverable to Mikuni) and decide whether to shift to production.*

#### **(2)Application**

*This section shall be applied to parts ordered by Mikuni. However, parts that have high commonality with conventional products can be excluded.*

#### **(3)Requirements :**

- a. *Implement transition to production judgement after Pre-production and before production scheduled date of the first production.*
- b. *The following items are input in the corresponding range for transition to production judgment.*
  - *Status of development history log*
  - *Result of purchased parts inspection.*
  - *Results of in-house manufactured parts inspection.*
  - *Results of Pre-production*
  - *Status of documents to use process control such as Packaging specification, Control, Parts Inspection Standard, Work Instruction and various masters etc.*
  - *Result of process capability.*
  - *Results of measurement system analysis.*
  - *Result of Process FMEA.*
  - *Response to problems and issues detected in the past (lesson learned).*
  - *Advanced Product Quality Timing Plan*
  - *Plan of Initiation Control*
- c. *Based on the above results, it is determined whether it is possible to shift to production from the viewpoint of whether it is possible to stably produce parts that meet the requirements, and the results are recorded.*

#### **(4)Report to Mikuni**

<i>Items</i>	<i>Description</i>
<i>Submission</i>	<i>Record of transition to production judgment</i>
<i>Subject</i>	<i>Transition to production judgement</i>
<i>Submission form</i>	<i>Appendix 8 (MID-Q06-001)</i>
<i>Submission</i>	<i>Specified date</i>

date	
Submit to	Purchase
Original / Copy	Copy

### 3.7.7 Submission of Part Inspection Report

(1) Objective

The objective is to prove that inspection and test are performed appropriately and parts shipped meet the requirements by objective evidence.

(2) Application

This section shall be applied to parts ordered by Mikuni.

(3) Requirements

- a. Include the items defined in the table below without omission into Part Inspection Report submitted to Mikuni. However, item that is not affected by any change can be omitted when design change or process change is made.

Items	Contents / No. Of Data	For prototype	For mold inspection	First product*		For Periodic inspection
				Formed & fabricated material	Non-formed & fabricated material	
Substances of concern (SOC)	Contained or not contained	✓	✓	✓	✓	✓
Material used	Conformity to materials specified (material certificate, etc.)	✓	✓	✓	✓	✓
All quality characteristics defined in part drawing and assembly drawing (Attach the samples that can refer the data measured).	n=1	✓			✓	
	n=1 per each cavity		✓			
Special characteristics (See 3.3.1)	n=30 and process capability (Cpk)			✓	✓	✓
Inspection item specified in Part Inspection Standard (See 3.7.3)	n=5			✓	✓	✓

\* The parts that the deviation was expired or that the designation of the acceptance without inspection was withdrawn shall apply the classification of first product. In addition, reduction and exemption of inspection item and/or contents/number of data is accepted only when obtaining agreement with Mikuni in these cases.

- b. Fill in the continuous variable unless there is justifiable reason if continuous variable can be obtained by inspection specified. Fill in the inspection result (OK/NG) for individual inspection sample if continuous variable cannot be obtained.
- c. Fill in the identification of relevant data into Part Inspection Report when relevant data is attached.
- d. PDI Report will be submitted for every dispatch / lot in Mikuni given PIS report format.

(4) *Submission to Mikuni*

<i>Items</i>	<i>Description</i>
<i>Subject</i>	<i>Parts applicable to any one of following</i> <ul style="list-style-type: none"> <li>– <i>Parts ordered as prototype,</i></li> <li>– <i>Sample for mold inspection,</i></li> <li>– <i>First product (Until specified as acceptance without inspection, each time the production lot of parts shipped is switched),</i></li> <li>– <i>Parts specified for periodical inspection (Until specified as acceptance without inspection, each time the production lot of parts shipped is switched).</i></li> </ul>
<i>Submission form</i>	<i>Appendix 7-1 or Appendix 7-2</i>
<i>Submission date</i>	<i>Specified delivery date of subject parts</i>
<i>Submit to</i>	<i>Attachment to parts delivered</i>
<i>Original/copy</i>	<i>Copy</i>
<i>Others</i>	<i>Identify the first product every packaging by using Identification Tag for First Product (Form 8, Other format is acceptable if all items prepared are contained, but color shall be yellow).</i>

**3.7.8 Submission of Part Submission Warrant**(1) *Objective*

*The objective is to declare that parts and manufacturing process meet Mikuni's requirements and to claim Mikuni's approval about the start of delivery for production at Mikuni prior to delivery of first product.*

(2) *Application*

*This section shall be applied to parts ordered by Mikuni.*

(3) *Requirements*

- a. *Prior to submission, confirm that parts produced meet all requirements specified in design document issued by Mikuni and its manufacturing process meets Mikuni's requirements.*
- b. *Consult with relevant function of Mikuni in advance if it can be expected that approval by Mikuni is not obtained.*
- c. *Re-submit Part Submission Warrant after taking appropriate measures if approval by Mikuni cannot be obtained.*

(4) *Submission to Mikuni*

<i>Items</i>	<i>Description</i>
<i>Submission</i>	<i>Part Submission Warrant</i>
<i>Subject</i>	<i>All parts (Excluding the parts that part number begins with X or F)</i>
<i>Submission form</i>	<i>Appendix 9 (Fill in the items prepared without omission)</i>
<i>Submission date</i>	<i>5 days before delivering first product (new drawing, change drawing, process change)</i>
<i>Submit to</i>	<i>Quality Control Dept.</i>
<i>Original/copy</i>	<i>Original (The original is returned after Mikuni checked. / If subject part is ordered by multiple Mikuni's sites, submit a copy containing Mikuni's decision, to site after 2nd)</i>

### 3.8 **Production**

#### 3.8.1 **Initiation control**

(1) **Objective**

*The objective is to collect the information by establishing special system different from stable production stage and to achieve early stabilization of quality and further quality improvement at production initiation stage.*

(2) **Application**

*This section shall be applied to parts ordered by Mikuni. But application to parts having higher commonality with conventional part may be excluded.*

(3) **Scope : Announce the IFC in all the below given condition :**

*Drawing Dimension Change  
Installation or changes in machines / equipments.  
Process Sequence / Layout change.  
Raw material change.  
Relocation of Production facilities.  
New Similar Parts/New Tool for Existing Part)  
New Part /New Product (Without Previous Exp.)*

(4) **Requirements**

- a. *Determine the period of initiation control based on the period necessary for data collection, the period considered necessary for achieving objectives as well as Mikuni's requirements. IFC period is decided in CFT meeting (3 lots min./ 3 months max. or as per customer requirements).*
- b. *Include appropriately the following considering result of pre-production into initiation control and determine the release criteria before start of initiation control.*
  - *Management by objectives,*
  - *Special inspection (addition of inspection item or increase in inspection frequency),*
  - *Study of process capability (See 3.3.2),*
  - *Aggregation and analysis of nonconforming parts,*
  - *Self process audit.*
- c. *Maintain the records about results of initiation control (Including measures taken for detected problems and issues) and release of initiation control.*
- d. *Criteria for termination of Initial Supply.*
  - (1) *Rejection level at customer line (Zero PPM).*
  - (2) *Capability study Results more than  $\geq 1.67$ .*
  - (3) *Customer complaint at IFC period Zero nos.*
  - (4) *In house rejection PPM (as per target) : trend should not be increasing.*
  - (5) *NC raised during product and process audit remains closed with action.*
  - (6) *Effectiveness of countermeasure taken during production preparation should be effective.*
  - (7) *Effectiveness of countermeasure taken during IFC should be effective.*
  - (8) *Incoming rejection (as per target) : trend should not be increasing.*
- e. *Any new problem arising during the initial supply control are also resolved. Monthly monitoring of IFC to be done and if any of the above requirements fails to meet then, IFC will extend/restart.*

*Supplier has to submit the Initial Flow Control Announcement & Termination sheet Appendix 8 (MID-Q08-001)*

### 3.8.2 Securing of traceability

(1) Objective

The objective is that when nonconforming parts occurred or flowed out, narrowing of suspected range that nonconforming parts are mixing by securing traceability from receiving material to delivery makes possible.

(2) Application

This section shall be applied to parts ordered by Mikuni.

(3) Requirements

- a. Identify the manufacturing lot and clarify its unit, in all stages from acceptance to delivery.
- b. Implement first-in first-out without fail including raw material or child part.
- c. Maintain the records about information required to trace the manufacturing lot of parts delivered (information to identify when received, when manufactured and when shipped).
- d. The size of the production lot is determined within the range of production under equal conditions, such as material lot, heat treatment lot, processing conditions, production shift, inspection frequency, etc. (In order to reduce the treatment range of a shipped product when a nonconforming product has been shipped, it is desirable to reduce the production lot according to the risk.).
- e. Maintain documented information in a format that allows search of production lot history within 2 hours of inquiries from Mikuni

### 3.8.3 Proposal for design change

(1) Objective

The objective is that when supplier desires design change for part drawing and assembly drawing issued by Mikuni, design change shall be requested to Mikuni and implemented if possible.

(2) Application

This section shall be applied to parts ordered by Mikuni.

(3) Requirements

- a. Propose to Mikuni and receive the decision of propriety of adoption if desiring design change for solving the manufacturing problems of parts ordered by Mikuni.
- b. Explore the root cause of requiring design change and consider its solution, prior to proposal. Include also the consideration of solutions not dependent on design change into this consideration. In addition, estimate objectively the benefit obtained through solution of problems.
- c. Submit the data to prove adequacy and validity of proposal contents as much as possible. In addition, consult with relevant function of Mikuni in advance if necessary.

(4) Request to Mikuni

Items	Description
Submission	Design change request
Subject	Proposal for Design Change
Request form	Appendix 10 (Fill in the items prepared without omission)
Request date	Not specified
Request to	Purchase Dept.
Original/copy	Original

### 3.8.4 Control of process change

#### (1) Objective

The objective is that when process change is performed by any reason (intentionally changing elements of manufacturing process including machine, material and method), occurrence or outflow of parts that cannot meet the requirements are prevented by planning change and controlling appropriately.

#### (2) Application

This section shall be applied to parts ordered by Mikuni.

#### (3) Requirements

- a. Formulate the concrete plan for process change and manage its progress. In addition, implement appropriately the quality inspection after process change (Compare before and after process change, if applicable).
- b. Implement process change after obtaining permission from Mikuni if applied to process change that the request to Mikuni is necessary.
- c. Submit the data to prove adequacy and validity of request contents as much as possible. In addition, consult with relevant function of Mikuni in advance if necessary.
- d. Prior to implementation, perform the related risk analysis (process FMEA etc.) and review related documents (Control Plan, Part Inspection Standard, Work Instruction, etc.).
- e. Validate the impact of the change on the manufacturing process. Therefore, quality confirmation (production trial run) should be performed whenever possible.
- f. Maintain the records about contents of process change, implementation date and quality confirmation result (validation of the changes, necessary actions) after process change.
- g. Submit declaration of change management on monthly basis to Mikuni India as per prescribed format Appendix 18 (MID-006-001)

#### (4) Request to Mikuni

Items	Description
Subject	Process change to fall under any one of following that may affect quality, in all processes from acceptance to delivery (Excluding process change resulting from design change) Change of manufacturing location (Including layout change), Change, addition or exclusion of process sequence, Change of production method or inspection method, Specification change or replacement of equipment or jig/tool (Including mold), Change of manufacturing setting or equipment setting, Change of material (material manufacturer), New use, change or disuse of subcontractor.
Request form	Appendix 11 (Fill in the items prepared without omission)
Request date	4 months before change planned (If it cannot be requested before request date, talk with Mikuni)
Request to	Purchase Dept.
Original/copy	Original



## Reference 7 (Manufacturing process change required process change request to Mikuni)

Division	Major classification	Middle classification	Minor classification	
Machine	Manufacturing location	Relocation outside the plant / facility		
		Relocation in the plant / facility	Floor layout change of manufacturing process	
			Change of manufacturing process sequence	
	Equipment in production process, measuring instruments, equipment (including inspection equipment)	New installation, expansion		
		Renew		
		Modification (including modification of command unit and power source)		
		Changes in the conditions of manufacturing and inspection equipment and parameters (except for daily adjustment)		
		Change (equipment A → equipment B, measuring instrument A → measuring instrument B)		
	Mold (including mold used to manufacture child parts)	New installation, expansion		
		Renew		
		Modification (including change of plan)		
	Tools (excluding molds, including inspection and test tools)	New installation, expansion (except for general-purpose tools)		
		Renew (except general-purpose tools)		
		Modification		
		Change (Tool A → Tool B)		
	Measuring tool for inspection	New installation, expansion (except for general purpose gauges)		
		Renew (except for general purpose gauges)		
		Modification		
	Method	Work method	Production method	
			Addition of manufacturing processes (including new installation and expansion)	
			Inspection method (including change of frequency)	
			Change of management standard at the time of manufacture	
			Process flow	Combine (consolidate) manufacturing processes
Divide manufacturing process				
Abolish manufacturing process				
Transport (child parts, work in process, finished goods)			Change of in-process transfer route	
			Change of method	
			Change of packing style	
			Change of child parts supply method (order supply etc.)	
Storage (child parts, work in progress, finished goods)			New location and expansion	
			Change of place	
Material	Materials (including element of parts such as paints and lubricants)	Adoption of new materials		
		Change of Sub-supplier, manufacturer		
		Change of type, ingredient and amount		
		Shape change		
		Change of supply / self-sufficiency		
	Auxiliary materials (except those not in contact with parts)	Use of new auxiliary materials		
		Change of manufacturer		
		Change of type or ingredient		
	Sub-supplier	Change of usage		
		Addition (including the addition of production site in sub-suppliers)		
		Change (including change of production site in sub-suppliers)		
		Change of parent organization (merger or subsidiary)		
	Changes in in-house production and out-of-house production			
	Environment	Change of environmental conditions such as temperature, humidity, illuminance		
		Change of special clothing (clean clothes etc.)		

Change Item	Change Details (Incase of Change)	MID Approval	
		Reqd	Not Reqd
<b>Man</b>	Extended shift working		<input type="radio"/>
	Extra shift working		<input type="radio"/>
	Contract manpower		<input type="radio"/>
	Skill level change (Regular)		<input type="radio"/>
	Organisation structure change		<input type="radio"/>
	New joinee		<input type="radio"/>
	Operator change		<input type="radio"/>
<b>Material</b>	Different spec / grade	<input type="radio"/>	
	Raw material size/thickness/weight	<input type="radio"/>	
	Different raw material approved supplier	<input type="radio"/>	
	Different raw material unapproved supplier	<input type="radio"/>	
	Child-part change (Machine)	<input type="radio"/>	
	Child-part change (Method)	<input type="radio"/>	
	Child-part change (Supplier)	<input type="radio"/>	
	Child-part change (Material)	<input type="radio"/>	
	Child-part change (Temperory Deviation)	<input type="radio"/>	
	Child-part change (Permanent Deviation)	<input type="radio"/>	
<b>Method</b>	Any temperory deviation from PCS	<input type="radio"/>	
	Process sequence change	<input type="radio"/>	
	New Technology	<input type="radio"/>	
	Sub-process supplier change	<input type="radio"/>	
	Additional process	<input type="radio"/>	
	Bin/Trolley (WIP/Storage)		<input type="radio"/>
	Packaging change	<input type="radio"/>	
	Transportation mode change		<input type="radio"/>
	Number of material handling		<input type="radio"/>
	Any change in WIP		<input type="radio"/>
	Traceability (Batch code) marking change	<input type="radio"/>	
	Inspection method	<input type="radio"/>	
	Inspection frequency	<input type="radio"/>	
	Inspection marking change	<input type="radio"/>	
Limit sample change	<input type="radio"/>		
Inspection equipment	<input type="radio"/>		
<b>Machine</b>	Tool change/modification/Renew	<input type="radio"/>	
	Die change	<input type="radio"/>	
	Machine change	<input type="radio"/>	
	Jig , fixtures & Mold change/modification /Renew	<input type="radio"/>	
	Removal / Addition of Pokayoke	<input type="radio"/>	
	Change in manufacturing condition /Machine parameter change	<input type="radio"/>	
	Power source change (non-routine)		<input type="radio"/>
<b>Manufacturing Location</b>	New location	<input type="radio"/>	
	Work station change		
<b>Environment</b>	Change of environmental conditions such as temperature, humidity, illuminance		<input type="radio"/>
	Change of special clothing (clean clothes etc.)		<input type="radio"/>

### **3.8.5 Control of variation point**

#### *(1) Objective*

*The objective is that when any variation point (passive varying element of manufacturing process including man, machine, material and method, or quality of parts outputted from process) occurs in process, supplier reacts to variation appropriately and prevents occurrence or outflow of parts that cannot meet the requirements.*

#### *(2) Application*

*This section shall be applied to parts ordered by Mikuni.*

#### *(3) Requirements*

- a. Define and implement the responsibility and authority as well as control procedure to control the variation point occurred in all processes from acceptance to delivery.*
- b. Investigate immediately the condition of process, and eliminate the variation points or take the additional reactions indispensable to supply the parts meeting requirements stably when noticing any change occurred in process.*
- c. Perform appropriately the retroactive inspection of parts produced before noticing variation for quality characteristics that might be affected by variation point.*
- d. Report immediately the reactions taken for variation to person having responsibility and authority to react to variation point.*
- e. Maintain the records about contents of variation, measures taken and result of quality check (Including retroactive inspection). and the result of confirming that the parts produced after responding to the change meet the requirements.*

### **3.8.6 Control of nonconforming parts**

#### *(1) Objective*

*The objective is to prevent erroneous use or shipment of nonconforming parts or suspect parts of nonconformity.*

#### *(2) Application*

*This section shall be applied to parts ordered by Mikuni.*

#### *(3) Requirements*

- a. Handle the parts that are suspicious of nonconformity as nonconforming parts until it is determined to be not the nonconformity. Suspicious parts include but is not limited to the following.*
  - Parts and materials that have exceeded the specified storage period.*
  - Parts up to the previous verification that were produced or inspected using equipment or measuring instruments and measuring tools that were determined to be abnormal by verification.*
  - Parts up to the time of the last start-up verification, which were measured by the inspection machine that did not judge a defective sample at the time of start-up verification.*
  - Parts that have no clear identification and unknown features.*
- b. Perform immediately the clear identification of nonconforming parts detected to prevent mixing into conforming parts.*
- c. Define clearly the controls and related responsibilities and authorities to deal with nonconforming part in advance. Report immediately the information of nonconformity to person having responsibility and authority immediately when nonconforming part is detected.*
- d. Control methods for the treatment of non-conforming parts are to educate and understand all appropriate manufacturing personnel.*
- e. Notify immediately to Mikuni Purchase Dept. And receive the instruction when noticing that nonconforming parts or suspicious parts were shipped.*
- f. Maintain the records about contents of nonconformity, quantity and measures taken.*

### **3.8.6.1 Control of reworked product**

#### **(1)Objective**

*The objective is responding appropriately to rework of the manufactured parts (operation to be carried out with a normal process or equivalent equipment and tools, and work to be carried out for lacking work and nonconforming products, as per the design specifications), Prevent occur or outflow parts that do not meet the requirements.*

#### **(2)Application**

*This section shall be applied to parts ordered by Mikuni.*

#### **(3)Requirements**

- a. *Perform risk analysis (recognize the risk and decide the countermeasure) in the rework process prior to a decision to rework the parts (It is desirable to include the risk analysis in advance in the process FMEA. Rework products include but is not limited to the following.*
  - *Wipe off grime.*
  - *Disassembly / reassembly (not including repressing and rewelding)*
  - *Additional work (in the case of using the same tool or equivalent equipment as the regular process, manual operation such as scraper or file)*
  - *Readjustment*
  - *Component replacement*
  - *Repaint*
- b. *Verify that the effects of the rework meet the dimensional tolerances and performance specifications.*
- c. *Prepare and educate rework instructions to required personnel and the instructions are can be used on rework area.*
- d. *Proper identification and details of reworked parts.*

### **3.8.6.2 Control of repaired products**

#### **(1)Objective**

*The objective is that appropriately respond to repair (restoration work using a method that is different from the regular method or make it different from the design specification) of manufactured parts and prevent the occurrence and outflow of parts that do not meet the requirements.*

#### **(2)Application**

*This section shall be applied to parts ordered by Mikuni.*

#### **(3)Requirements**

- a. *Identify the risk through risk analysis in the repair process and determine the countermeasure prior to a decision to repair the parts. (It is desirable to include the risk analysis in advance in the process FMEA for risk analysis and reflect to Control Plan. Repair products include but are not limited to the following.*
  - *Restoration of screw hole with different tool and method from regular process, use helisert.*
  - *Additional machining such as edge cutting, hole diameter enlargement, and chamfering by tools and methods different from regular process.*
  - *Re-press fit of press-fit parts*
  - *Re-welding of welded parts*
  - *Application of adhesive, metal cement etc. (Not in regular process)*
- b. *Notify our purchasing department before starting repair and receive instructions (If notification has already been incorporated into the Control Plan and approved by Mikuni, no notification is required).*
- c. *Verify that the impact of the repair operation meets the dimensional tolerances and performance specifications.*
- d. *Prepare and educate rework instructions to required personnel and the instructions are can be used on rework area.*
- e. *Ensure traceability including the number of repaired parts, treatment details, treatment date, etc. with*

identification mark.

### 3.8.7 Deviation request / Deviation Request

(1) Objective

The objective is that when shipping the parts that are not meeting requirements or that were produced in process that is different from currently approved, to receive the official permission from Mikuni and secure the traceability of parts delivered.

(2) Application

This section shall be applied to parts ordered by Mikuni.

(3) Requirements

- a. Request in advance and obtain Mikuni's permission, when desiring shipment of parts that are not meeting requirements or that were produced in process differing from process approved currently.
- b. Deliver the deviated parts (excluding the parts permitted deviation until replacement of the mold) given Mikuni's official permission to Mikuni Quality Control Dept. by attaching Part Inspection Report including the following and copy of Deviation Request returned from Mikuni, for each delivery lot.
  - The quality characteristic that subjected to deviation
  - The quality characteristic that is affected by the quality characteristics that subjected to deviation
  - The quality characteristic that the special instruction is given by Mikuni on the deviation
- c. Bear the total amount of incidental cost (investigation or verification cost, additional control cost, production or processing cost for relevant parts, etc.) resulting from deviation according to a claim from Mikuni.

(4) Request to Mikuni

Items	Description
Subject	When desiring shipment of parts that are not meeting requirements or that were produced in process different from process currently approved and satisfying all following conditions <ul style="list-style-type: none"> <li>– Effect on function, performance, commodity value and compatibility is negligible,</li> <li>– Safety and conformity with government regulation are not spoiled and there is also no fear for product liability (In principle, deviation for special characteristics (See 3.3.1) is not permitted),</li> <li>– Same nonconformity has not been permitted the deviation in the past (In principle, deviation for same nonconformity shall be permitted only once).</li> </ul>
Request form	Appendix 12 (Fill in the items prepared without omission)
Request date	Planned delivery date of subject parts (If it is requested after delivery, talk with Mikuni)
Request to	Purchase Dept. (If subject part is delivered to multiple Mikuni's sites, the requests to each site are needed)
Original/copy	Original
Others	Identify deviation parts every packaging by using Identification Tag for Deviation (Form 13, Other format is acceptable if all items prepared are contained, but color shall be pink).

**3.8.8 Reaction for nonconformity of parts already delivered****(1) Objective**

*The objective is to contain by taking appropriate initial response for nonconformity of parts already delivered and prevent recurrence of nonconformity by implementing of corrective action precisely.*

**(2) Application**

*This section shall be applied to parts ordered by Mikuni.*

**(3) Requirements**

- a. *Implement appropriately the measures required such as an inspection of parts already delivered and inventory (Including similar parts and process appropriately), repair and delivery of substitute for nonconforming parts while communicating with Mikuni, when receiving the notice of quality nonconformity of parts already delivered by Mikuni.*
- b. *Investigate the cause for nonconformity of parts already delivered, implement immediately the appropriate countermeasures to eliminate the cause, and confirm their effectiveness thereafter. Reflect these countermeasures into appropriate documents such as internal regulations, Design FMEA (See 3.5.2), Process FMEA (See 3.6.2), Control Plan (See 3.7.2), Part Inspection Standard (See 3.7.3) and work instructions (See 3.7.4). Submit the countermeasure to MID within one month or per MID given timeline (exception case)*
- c. *Apply appropriately the countermeasures to eliminate the cause of nonconformity to also similar parts and process.*
- d. *Maintain the record about cause of nonconformity and countermeasures taken.*

**(4) Report to Mikuni**

<i>Items</i>	<i>Description</i>
<i>Submission</i>	<i>Corrective Action Report</i>
<i>Subject</i>	<i>Nonconformity specified by Mikuni</i>
<i>Report form</i>	<i>Appendix 14 (Fill in the items prepared without omission) , if there is a request to use the form specified by our customer, it will be instructed separately)</i>
<i>Report date</i>	<i>Specified date</i>
<i>Report to</i>	<i>Purchase Dept.</i>
<i>Original/copy</i>	<i>Original</i>

### 3.8.9 Change freeze period

(1) Objective

- a. The objective is to reduce the various changes which may become the inhibiting factors of stabilization of manufacturing process at the stage of production start-up in Mikuni to achieve early stabilization of quality.
- b. Another objective is to promote early finding and removing of the problems and issues through the existence of freeze period and to attempt early polishing up of the parts and manufacturing process.

(2) Application

*This section shall be applied to parts ordered by Mikuni.*

(3) Requirements

- a. The change freeze period is indicated in the table below.

Classification	Change freeze period*
Design change	Start : Design validity assessment (achieving approval) Expiry : 3 months later of the start of production (Until it is released if the initiation control is not released)
Process change	Start : Pre-production Expiry : 3 months later of the start of production (Until it is released if the initiation control is not released)
Supplier change	

\* The start and expiry of change freeze period which are indicated in the table above shall be adopted the point of time at the production activities in Mikuni.

- b. The change during the change freeze period is not accepted in principle. But the change during the change freeze period is accepted only for satisfying customer requirements or when there is an other unavoidable reason. In this case, an application to Mikuni shall be implemented before the change and the change becomes possible after approval by Mikuni.

### 3.8.10 HAZARDOUS CHEMICAL CONTROL DECLARATION :

Supplier must submit the Hazardous Chemical Control Declaration on yearly basis. Appendix 8 & 8(B) MID-Q06-03) .and follow the Green Procurement Guideline of MID.

### **3.8.11 SUPPLIER QUALITY AND DELIVERY EVALUATION :**

*Objective : MID shall inform suppliers the results of quality and delivery of supplied parts. Supplier shall monitor the result performance, verify the attainment of the target and continuously improve the quality & delivery of supplied parts.*

*Application : This section shall be applied to all the parts ordered by MID.*

*Requirement : Supplier shall monitor the Supplier Performance report evaluated by MID each month.*

*Following parameters will be considered for performance evaluation :*

- 1. Ontime delivered product conformity.*
- 2. Customer disruptions at the receiving plan (including yard holds and stop shipments)*
- 3. Delivery schedule performance.*
- 4. No of occurrence of premium freight.*
- 5. Special status, customer notification related to quality, delivery, warranty and feild returns.*

#### **EVALUATION CRITERIA :**

- 1. 120 ~ 108: Rank 1 – Good, no action required.*
- 2. 108~96: Rank 2 – Average, no action required.*
- 3. 96 ~ 84: Rank 3 – Acceptable with improvement action plan.*
- 4. 84 ~ 72: Rank 4 – Not acceptable, Need immediate countermeasure.*
- 5. 72 or Below : Rank 5 – Worst Supplier, Re-evaluation required.*

*Minimum required rank by MID : Rank 3*

**WORST SUPPLIER CRITERIA :** *Any supplier who falls in the below given criteria will be declared as WORST SUPPLIER by MIKUNI :*

- 1. Supplier Overall rating less than 60% for continously 3 months.*
- 2. More than 3 IQI in a month for continously 3 months.*
- 3. Same quality issue raised more than twice in a month.*

*Any supplier who falls in worst supplier criteria has to submit the improvement action plan and MIKUNI will verify the effectiveness*

### **3.8.12 SUPPLIER QUALITY AUDIT :**

**Objective :** *To conduct quality audits at supplier's site. Supplier shall participate in the quality audit and take appropriate actions with respect to the findings identified for quality improvement.*

*Application : This section shall be applied to all the suppliers.*

*Requirement : Mikuni will conduct system and process audit.*

*There are two types of audits : A regular audit and an occasional audit conducted by Mikuni.*

**Regular Audit :** *Supplier subjected to regular audit shall be selected from among those with whom Mikuni has entered into the general agreement for purchase of parts.*

*Mikuni wil communicate audit date and details to supplier 15 days prior to the audit.*



2. *Supplier shall, based on a regular audit report issued by Mikuni, formulate an improvement plan and submit to MIKUNI by the specified date. MIKUNI may request changes to the implementation plan where necessary.*

**Improvement Audit :** *Of those which correspond to the following criteria, a supplier's quality audit which will be conducted when deemed necessary by MIKUNI and this will be performed by specifying the scope of conformation and verification in accordance wth the purpose of the audit.*

1. *Continous 5 lots rejected from vendor.*
2. *More than 2 IQI for the same part raised in a month.*
3. *Any customer claim related to the vendor parts.*
4. *Nos of NC's more than 25 in the regular audit.*

2. *Supplier shall, based on audit report issued by Mikuni, formulate an improvement plan and submit to MIKUNI by the specified date. MIKUNI may request changes to the implementation plan where necessary.*

***END***