Revision History

Rev No	DCN #	Changes	Effective Date	Approved
01	0006	Initial release	08/06/04	MY
02	0017	Modification of procedure	10/08/04	MY
03	0046	Update procedure for product hold	10/19/04	MY
04	0071	Modification of flowchart	11/30/04	MY
05	0627	Clarify the authority of disposition of non-conforming products	01/24/09	YC
06	0718	Change process owner & format	07/28/09	YZ
07	0966	Switched portion of contents to MRB Procedure, re-wording, re-defined the major non-conforming, Delete Form Q004.	04/13/11	A. Qin
08	1169	Yearly reviewing without change	05/20/13	A. Qin
09	1198	Change process owner	05/28/14	H. Li

Non-conforming Product Control Procedure

Process Owner: Hui Yao Date: 05/12/14

Department Manager: Hong Li Date: 05/23/14

1.0 Purpose

This procedure establishes the requests to ensure that the non-conforming products are properly identified, segregated, and controlled to prevent the unintended use or delivery.

2.0 Scope

This procedure applies to non-conformities found during all product realization processes.

3.0 Authority and Responsibilities

• Inspection person of all departments	• Identifies and segregates non-conforming products. • Reports findings to his/her supervisor when necessary. • Fill out the Non-conforming Material Report Form.
• QA	• Conduct the MRB meeting. • Issues Corrective Action Request when necessary.
• Customer Service	• Informs customer if the non-conforming affects delivery schedule. • Works with customer to arrange field recall when needed.
• Production/ Responsible Teams	• Verifies conformance of held and recalled products • Identifies proper corrective action to reduce/eliminate the occurrence of non-conforming material

4.0 Definitions and Acronyms

CAR:	Corrective Action Request
MRB	Material Review Board

5.0 Flow Chart of Procedure

Flow Chart	Responsible	Notes	Form
Identify the non-conforming Products	IQC, IPQC, OQC, Production, ets.	• Identify the products that are not conform to product requirements	Refer to Product Identification and Traceability Procedure (QP 75301)
↓ Segregate the Non-conforming Products	IQC, IPQC, OQC, Production, ets.	• Segregate the Non-conforming products by areas or trays and not mixed with OK products	
↓ Clarify the Range of Products with the Same Symptoms	Production, QA Engineering, etc.	• Check, trace and confirm the products with same symptoms	
↓ Forward the Non-conforming Products to MRB	IQC, IPQC, OQC, Production, ets.	• Timely forward the non-conforming product to MRB	Refer to MRB Procedure (QP 83002)
↓ Conduct the MRB Meeting	Members of MRB		
↓ Implement the Disposition Plan of MRB Meeting	Related Departments		
↓ Initiate the Corrective Action Request	QA	• Request the correction and prevent the re-currencites	Refer to Corrective and Preventive Action Procedure (QP 85201)

6.0 General Requirements

6.1 The Definition of Nonconforming Products

The non-conforming products are those products that not meet the pre-defined criteria or specifications.

The non-conforming products are found during the incoming inspection stages, in-process inspection stages, final inspection stages, out-going inspection stages, contractor manufacturing site and in the customer field.

6.2 Identification on the Non-conformity Products

Once the non-conformity products are found, the responsible department shall make identification on them timely.

6.3 Segregation or Purge on the Non-conforming Products

The non-conforming products shall be segregated from the normal conforming product and prevent from unintended use.

If the nonconforming symptom had been confirmed, if necessary, QA will request the purge action and collect all of non-conforming products during different production stages/locations to the assigned area(s) and waiting for further dispositions.

The purge request are released from QA and supported by related departments. All non-conforming products after purge shall be collected and stored in a location with clearly identification.

The disposition of the non-conforming products that had been purged shall follow the decision from MRB meeting or further instructions from managements.

6.4 Classification of Non-conforming Products

The non-conformity event that has the high impact to the production or cost shall be handled with high-priority.

Level	Description of impact
Major	– High defect rate of the incoming lot compared with normal cases. – Defects impact that make the production line stop or delay. – Large yield drop or process yield is lower than normal.
Minor	– All other findings

6.5 General Guideline to Trace/Verify the Products

For the non-conforming products found, the Production and QA shall make evaluates severity of non-conformity of product/material, analyzes the impact of current finding to other similar products, escalate to top management if the issue is not resolved timely.

Case	Root cause of the Non-conformity	Trace/verify on the related products
# 1	The design of the product.	All product models based on the same design.
# 2	Non-conformity of raw material.	All products assembled with the same raw material batch.
# 3	The variance of current manufacturing process or using a unqualified process.	All products built during the period that the variance may occur.
# 4	Malfunction of manufacturing equipment (including testing equipment)	All products manufactured during the period that the malfunction may occur.
# 5	A consistent operation error of a specific operator such as using wrong material, and/or not following the work instructions	All products produced by the particular operator.

6.6 Actions on the Non-conformity with High Impact

When necessary, a team will be organized to handle the case of non-conforming with high impacts on concerns.

For general non-conforming that found in incoming or in-process inspection shall forwarded to MRB for further dispositions. Please refer to MRB Procedure QP 83002. Incoming Inspection Procedure QP 74301.

6.7 Actions on the Non-conformity Found on Customer Site

If the trace results show the non-conformity products will impact the contract manufacture or customers, a notification shall be released to the external parties by Customer Service.

Customer Service will work with customer in handling the case such as contamination plan, corrective actions, and recovery plan on the non-conformity in customer site. Please refer to the Customer Complaint Handling Procedure (QP 72002)

7.0 Reference Documents

QM-001	Quality Manual
QP 72002	Customer Complaint and RMA Procedure
QP 74301	Receiving Inspection Procedure
QP 75101	Process Control Procedure
QP 82402	Outgoing Inspection Procedure
QP 83002	Material Review Board Procedure
QP 85201	Corrective and Preventive Action Procedure