

Non-conforming Product & Material Handling Standards

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List of Document Modifications				
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20/05/2022	Initial release	Version A time 0	Version A time 0	Xiao Jianbin
10/03/2023	Changed the language from Mandarin to 3 languages, namely English, Mandarin and Indonesian.	Version A time 0	Version A time 1	MaWelei
09/10/2023	1. Revise the Document 2. Non-conforming product handling standards are added to the technical department to be responsible for the content 3. Divide the new version into three and rewrite it according to the Chinese, English, and Indonesian versions	Version A time 1	Version A time 2	Shi Meng Zhi
08/04/2024	To change PMC to Supply Chain and Quality Control to Quality.	Version A time 2	Version A time 3	Elia

1. Purpose

This implementation standard is used to standardize the processing process of unqualified materials found in incoming inspection during production operation, expired materials during storage, and unqualified materials and products found in the production process.

2. Scope

This implementation standard specifies the actions that need to be taken by the quality, production, Supply Chain, and technical departments when non-conforming products (including materials and products) are found. Cover the management standards of non-conforming products in the whole process. The semi-finished products produced during the production process are processed by the unqualified material treatment process. The non-conforming products covered by this standard are:

- Raw materials provided by third-party suppliers, performed by non-conforming material schemes
- Semi-finished products provided by third-party suppliers, performed by non-conforming material schemes
- Semi-finished products supplied by the company's in-house factory, carried out by non-conforming product schemes
- Products produced by the company and provided to third parties are executed by non-conforming product schemes

3. Definitions

- 3.1 Non-conforming materials – Raw materials or semi-finished products supplied by third-party suppliers that are found not to meet pre-specified quality standards during incoming inspection or production. Quality standards include physical, chemical, cosmetic or organoleptic criteria.
- 3.2 Non-conforming products – refer to semi-finished products or finished products produced in-house that fail to meet the quality inspection standards in the process. Or the factory quality inspection found that the quality standards required by the customer were not met. Quality standards include: physical, chemical, cosmetic or organoleptic criteria.
- 3.3 RCA – Root Cause Investigation, a root cause conclusion drawn through problem analysis

tools such as 5-Why, 6W2H, fishbone diagram, etc.

- 3.4 CAPA – Corrective and preventive actions. Corrective and preventive actions based on clear root cause findings. Corrective actions focus on making up for losses, and preventive actions are used to avoid the recurrence of the same problem.
- 3.5 AQL – Acceptable Quality Limit. A set of internationally accepted quality sampling standards defines the number and acceptable range of samples according to the severity and quantity of product defects.
- 3.6 Quality inspection failure – a quality accident caused by the discovery of unqualified quality indicators by sampling inspection during the production process. At the same time, this indicator cannot currently be monitored online quality.
- 3.7 Quality failure – quality accidents caused by unqualified product quality indicators found by online monitoring equipment during the production process. At present, it is not possible to ensure stable quality through the control of upstream processes.
- 3.8 Quality assurance failures – quality incidents that are not detected during production through sampling and online quality monitoring. It is usually a problem that is discovered during factory inspection.
- 3.9 Serious quality accidents – quality accidents found due to customer complaints, and the losses caused exceed xxx yuan. Serious quality incidents include any possible quality failures.

4. Responsibilities

4.1 General Manager

Ensure that the facility has sufficient resources to implement nonconforming management. In the event of a serious quality incident, it is the responsibility of the general manager to ensure the timely completion of the investigation. The general manager needs to submit the primary investigation report to the superior within 24 hours, determine the implementation plan according to the investigation report, and decide whether it is necessary to establish a product recall team to recall the batch of products.

4.2 Quality Director

Responsible for the implementation of non-conforming product handling standards. Arrange the

maintenance of implementation standards and the training and assessment of related standards, while continuously optimizing the implementation standards. When a serious quality accident occurs, the quality director needs to organize the establishment of an accident investigation team. At the same time, within 24 hours, the investigation conclusion of the accident will be written as a primary accident investigation report and submitted to the general manager for review. Complete the full survey and submit the full investigation report within 72 hours. If a product requires a recall, join the product recall team to provide relevant product information.

4.3 Director of Production

Approvers for the release of concessions to non-conforming materials and non-conforming products. Make a reasonable assessment of the impact of non-conforming materials on the product through the data provided by the quality department and the production risk, and decide whether to use non-conforming materials according to the evaluation conclusions; Through the data provided by the quality department and the product risk, the impact of the non-conforming product on the customer is reasonably evaluated, and the product can be shipped according to the evaluation conclusion. If there are non-conforming products that need to be shipped, they need to be recorded and archived after reaching agreement with the customer. When a serious quality accident occurs, the production director needs to cooperate with the quality director and allocate sufficient resources to investigate the cause and impact of the accident. Join the accident investigation team as the deputy team leader, provide all required production information and assist the quality director to complete the accident investigation report.

4.4 Quality Manager

Responsible for the implementation and improvement of the implementation standards for the management of unqualified materials and non-conforming products, and implement skills training at least once a year and evaluate the training results within the factory. Reduce the occurrence of quality accidents by continuously optimizing incoming inspection standards and product quality inspection standards to determine unqualified products. Responsible for providing accurate testing data and making recommendations for the concession release of non-conforming materials and non-conforming products. When quality failure occurs, assist the production department to continuously improve the relevant quality inspection, control and

assurance procedures.

4.5 Quality Department

Responsible for all unqualified materials and unqualified products in accordance with this implementation standard, timely put forward the modification of the implementation standard, and the quality manager to make corresponding improvements.

4.6 Production Sector

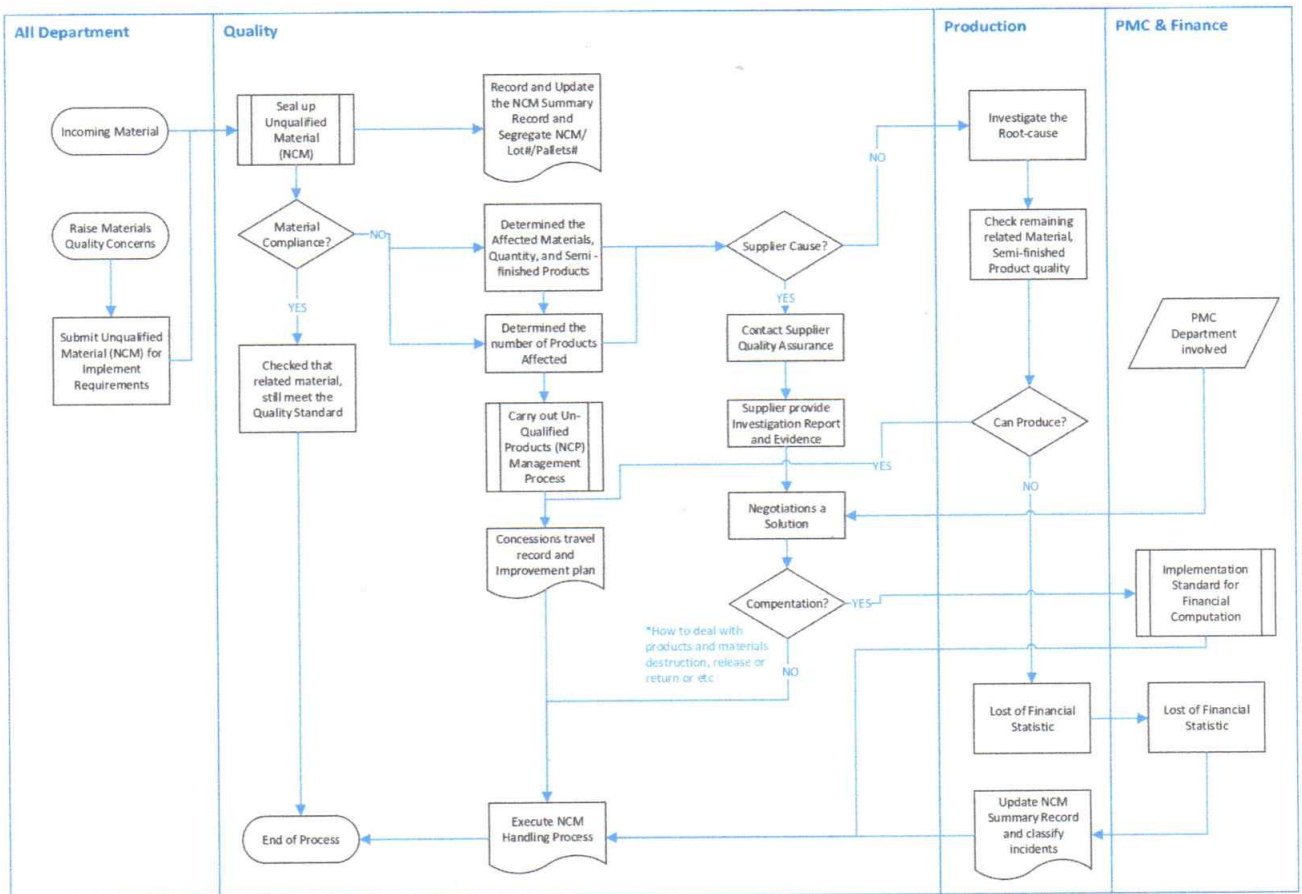
Responsible for putting forward unqualified material management requirements for materials in doubt in the production process, and responsible for putting forward management requirements for unqualified products for the quality risk of products in the production process. Actively take preventive measures against accidents that have already occurred to avoid the recurrence of similar problems.

4.7 Technical Sector

Responsible for sampling sensory inspection and judgment of incoming materials, semi-finished products and finished products, and cooperate with the quality department and production department to judge the compliance of materials and products and provide professional guidance for cause investigation.

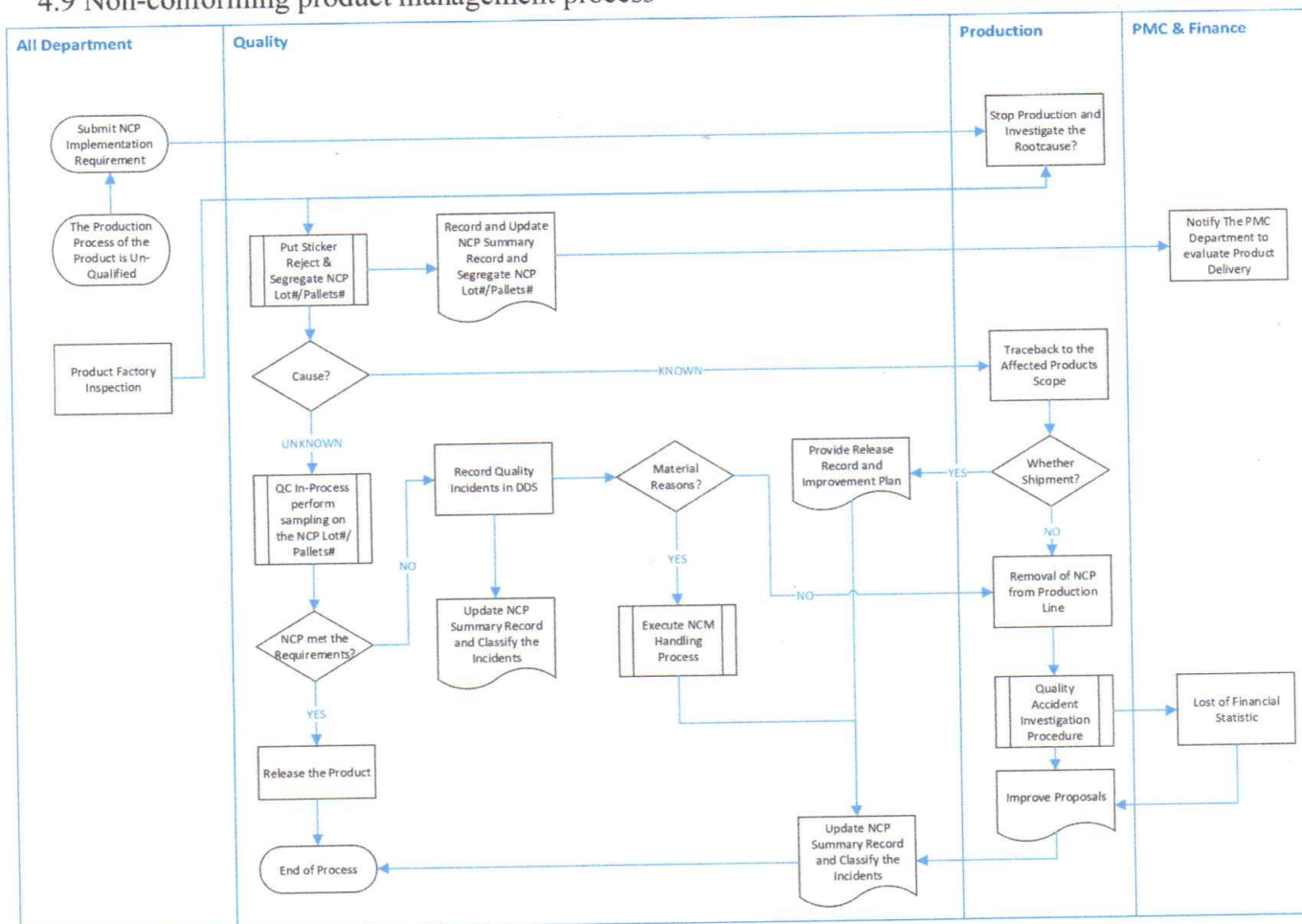
Flowchart

4.8 Non-conforming material management process



This process applies to raw materials and semi-finished products supplied by third-party suppliers. If the material involved has quality issues, this process should be followed.

4.9 Non-conforming product management process



This process applies to semi-finished products as well as finished products produced in the factory. If the products produced by the factory have quality problems, this process should be followed.

Execution steps for nonconforming material handling

4.10 Submission of Nonconforming Material Handling Process

All employees in the factory are able to request non-conforming material handling procedures for materials with quality problems. At the same time, the staff responsible for all sections and processes need to be responsible for the materials involved (such as warehouse personnel checking the outer packaging, production personnel checking the appearance quality, quality personnel inspecting incoming materials, etc.). The relevant personnel are trained in the process of handling non-conforming materials and clearly understand the steps that need to be performed. The Nonconforming Material Execution Record Form is owned by the quality department, which is responsible for maintaining and coordinating the completion and filing of the form. This

ensures consistency and uniqueness of relevant information.

Nonconforming material handling can occur for two reasons:

- When the quality department conducts incoming inspection, it is found that the relevant indicators of materials are unqualified;
- In the production process, due to the quality accident investigation, it was found that the cause was caused by material quality problems.

Whatever the reason, notify the quality department immediately. Timely seal the affected materials and products, and issue a non-conforming material execution record form to notify the relevant departments of the implementation of the unqualified material handling standard.

4.11 Verification of non-conforming materials

When non-conforming materials are found, all subsequent steps need to be confirmed by the quality department before they are performed. The verification methods involved can only be performed by the relevant personnel in the quality department.

After verifying the material quality issue:

- If the material has not been put into the production line, report it in time. Relevant departments and personnel evaluate the production situation and take corresponding measures to ensure that the subsequent production plan is adjusted to ensure that the production line will not be idle.
- If material problems are found in production, notify the quality department immediately. At the same time, the relevant materials and products are sealed, and the relevant materials are treated according to unqualified materials; The relevant products are disposed of as non-conforming products. At the same time, relevant departments and personnel evaluate the production situation and take corresponding measures to ensure the delivery of products.

4.12 Non-conforming materials due to internal reasons

If the material quality problem is caused by internal reasons, such as incorrect storage, access, transportation, etc., then the relevant department involved should investigate the cause of the problem and implement the corresponding corrective plan and preventive measures. The handling of relevant materials (e.g. picking, discarding, etc.) and related actions need to be fully recorded in the nonconforming material execution record sheet. The quality compliance team

tracks the implementation of relevant actions and records losses.

4.13 Non-conforming materials due to third-party suppliers

If the material quality problem is due to a third-party supplier. The facility shall immediately contact the supplier and request that the supplier respond to the investigation of the cause and corrective action and preventive actions within 5 working days. Corrective options include:

- The amount of material affected, the treatment of the batch
- Opinions on the recycling, return or disposal of materials
- When only the material itself (material that has not yet been put into production) is affected, the supplier shall provide the replenishment of the material and pay compensation for the purchase costs of the factory
- When more than the material itself is affected (e.g. finished product, internal rework, or additional action), the plant is contractually required to recover other losses. The quality department tracks the implementation of supplier-related actions and records losses.

Nonconforming product handling execution steps

4.14 Submission of Nonconforming Product Handling Process

All employees involved in the production process in the factory are able to request the disposal of non-conforming products with quality problems. At the same time, all personnel in the production process and those responsible for the link need to do relevant sampling inspections of the process parameters and semi-finished products and finished products in accordance with the quality inspection standards (such as production line employees, quality inspection personnel, material transportation personnel, etc.). The relevant staff need to be trained in the handling process of non-conforming products and clearly understand the steps that need to be performed. Typically, quality problems with semi-finished and finished products produced in-house are recorded as quality incidents. This record is owned by the quality department, which is responsible for maintaining and coordinating the recording and management of quality incidents, so as to ensure the consistency and uniqueness of relevant information. The record of a quality

incident must contain at least the following:

- The context of the accident, including product, time, quantity;
- Investigation records of the accident, including 5-Why or fishbone diagrams;
- Corrective plan and preventive measures for the accident and the corresponding time limit;
- Conclusions about the accident and product handling measures.

When the quality department proposes to dispose of non-conforming products, it needs to notify all relevant departments of the occurrence of this accident. This process is typically triggered for three reasons:

- In the production process, the relevant process indicators are out of control, the sampling inspection is unqualified, or the core components are damaged;
- Quality problems are found with the materials used;
- The factory quality inspection found that the product quality indicators were unqualified.

Regardless of the reason for the occurrence, notify the quality department immediately. Timely sealing of affected products, immediate execution of non-conforming product handling procedures and notification of relevant departments.

4.15 Classification and recording of quality accidents

Quality accidents need to be classified in the records of quality accidents, the purpose of which is to take corresponding measures for different categories of quality accidents and to define the person responsible for the task.

4.15.1 Quality Check Failure (QCF)

The quality accident defined by the quality inspection failure is for the situation where the quality of finished products and semi-finished products is found to be unqualified during the implementation of specified quality inspection tasks. After such incidents, production and quality departments should look for ways to improve. Automate inspections of inspection content as much as possible, or strengthen sampling standards.

If the enhanced sampling standard is adopted for a period of time, the same quality problems do not occur. Indicate that the improvement measures are effective, and at this time, the appropriate relaxation of the sampling criteria can be considered to

make the management quality more economical.

4.15.2 Quality Failure (QTF)

Quality accidents defined by Quality failure are for unqualified quality of finished and semi-finished products found by online control and online monitoring. After such accidents, the production department, technical department and quality department should seek to improve the monitoring equipment, process and technical parameters. Optimize upstream materials, testing equipment or control parameters to improve product stability.

The effectiveness of improvement measures is tested by relevant achievements:

- If the control failure is caused by unstable material quality, the material quality performance will be improved after the implementation of the improvement measures.
- If the control failure is caused by the instability of the monitoring equipment, the deviation of the relevant monitoring results is reduced after the implementation of the improvement measures.
- If the control failure is caused by incorrect control parameters, the standard deviation of the parameters is reduced after the implementation of the improvement measures.

After the improvement measures prove effective, the factory can discuss the improvement of the relevant standards to make them a requirement for future relevant content, and follow up the communication and implementation with stakeholders.

4.15.3 Quality Assurance Failure (QAF)

Quality assurance failure defines quality accidents for unqualified finished products and semi-finished products found during factory inspection. The reason for this is that the upstream process is not taken into account by quality inspection and Quality standards. Relevant inspection and control standards should be implemented immediately after such accidents. Relevant standards are discussed and implemented

by the quality department, production department and technical department.

4.15.4 Serious Quality Incident (SQI)

Any quality accident has the potential to become a serious quality accident. The criteria for defining serious quality incidents are for customers to complain about product quality problems and require compensation of more than \$100,000.

When a serious quality accident occurs, it shall be carried out in accordance with the serious quality accident handling process. The Quality Director evaluates the accident and sets up an investigation team. If a recall is required, a product recall working group is established.

At the same time, relevant complaints need to be recorded in product complaint records and customer complaint procedures implemented.

4.16 Methods of sampling inspection

After the preliminary definition of quality accidents, it is necessary to carry out relevant inspections on the affected finished products and semi-finished products to confirm the number and scope of affected products. The relevant inspection results are used to support the next step of the treatment of related finished products and semi-finished products. (e.g. concession release, rework, discard, etc.)

4.16.1 If the cause of the accident is clear

According to the actual situation, the quality department and the production department discuss the sampling method. Proper sampling frequency and coverage must be ensured, and all non-conforming products must be eliminated. The relevant sampling methods and test conclusions are used to support the next processing methods.

4.16.2 If the cause of the accident is unclear

In this case, the quality department and the production department first determine whether the affected product range is the current production batch or has exceeded the current production batch. The sampling criteria for the design need to be

implemented in accordance with the AQL.

SAMPLE SIZE CODE LETTERS							
Lot Size	General Inspection Levels			Special Inspection Levels			
	I	II	III	S1	S2	S3	S4
2 to 8	A	A	B	A	A	A	A
9 to 15	A	B	C	A	A	A	A
16 to 25	B	C	D	A	A	B	B
26 to 50	C	D	E	A	B	B	C
51 to 90	C	E	F	B	B	C	C
91 to 150	D	F	G	B	B	C	D
151 to 280	E	G	H	B	C	D	E
281 to 500	F	H	J	B	C	D	E
501 to 1200	G	J	K	C	C	E	F
1201 to 3200	H	K	L	C	D	E	G
3201 to 10000	J	L	M	C	D	F	G
10001 to 35000	K	M	N	C	D	F	H
35001 to 150000	L	N	P	D	E	G	J
150001 to 500000	M	P	Q	D	E	G	J
500001 and over	N	Q	R	D	E	H	K

ANSI/ASQ Standard Z1.4 - 2008

SINGLE SAMPLING PLANS FOR NORMAL INSPECTION															
Sample Size Code Letter	Sample Size	Acceptable Quality Levels (Normal Inspection)													
		0.065		0.10		0.15		0.25		0.40		0.65		1.0	
		Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
A	2														
B	3														
C	5														
D	8														
E	13														
F	20														
G	32														
H	50														
J	80														
K	125														
L	200														
M	315														
N	500														
P	800														
Q	1250														
R	2000														

↑ Use first sampling plan above arrow, if sample size equals or exceeds lot or batch size, do 100 percent inspection. ↓ Use first sampling plan below arrow
 AC : Acceptance number Re : Rejection number

Major defects are performed in accordance with the first level sampling standard, AQL1.0 standard;

Ordinary defects are performed in accordance with the second level sampling standard, AQL2.5 standard;

Minor defects are performed in accordance with the third pole sampling standard, AQL6.5 standard.

Samples need to be representative of the corresponding production batch, as random as possible. Avoid bias in results due to sampling methods.

4.17 Investigation and corrective and preventive measures for quality accidents

After the sampling inspection is completed, the production department needs to re-evaluate the cause of the accident. If necessary, 5-Why or fishbone diagrams can be used as analytical tools. Develop corrective and preventive actions based on the conclusions of the analysis.

Among them, corrective programs focus on immediate implementation of actions to reduce losses; Preventive measures focus on implementing continuous improvements to avoid the same problem from happening again.

All investigation conclusions, including the reasons and related measures, need to be recorded in the quality incident record. The quality compliance team ensures that all measures are completed on time and that improvements are accepted.

4.18 Disposal plan for non-conforming products

Based on the investigation conclusions and sampling test results, the quality department makes recommendations on product disposal plans. The production department decides on the disposal of the product based on the recommendations of the quality department, commercial considerations and risk assessment.

If the product in question is discarded: Financial statistics on losses and recording losses. Notify the relevant departments to make adjustments to the product delivery plan.

If the relevant product is reworked: Production counts losses and records losses. Notify the relevant departments to guide the rework work and adjust the production plan.

If the relevant product is compromised and released: notify the customer of the relevant investigation conclusion and obtain the customer's consent. Notify the relevant departments to make corresponding shipping arrangements.

4.19 Reporting of quality incidents

The quality department is responsible for the statistics of the occurrence of quality accidents, and at least monthly written reports on the performance of factory quality accidents. As part of continuous improvement efforts, the report needs to include key indicators of quality accidents, analysis of the causes of accidents, and evaluation of the effectiveness of relevant improvement

programs.

The quality department needs to continuously make improvements to the management of nonconformities in the factory and evaluate the cost and effectiveness of related improvement measures. Minimize the increase in production costs of related measures.

5. Related Quality Records

QR Number	Title
WII/QR03-60	NCM & NCP Label
WII/QR03-61	Non-conformance Material Form
WII/QR03-62	Non-conformance Product Form
WII/QR03-63	Non-conformance Material Summary Record
WII/QR03-64	Non-conformance Product Summary Record