R3402:
Regulations for Process Quality Control

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PRODUCTION DEPARTMENT

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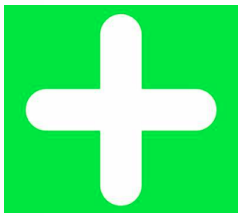
① Purpose of “Regulations for Process Quality Control”

Purpose

To **ensure the safety and quality** of **products** in each process by **clarifying the purpose** and **process of quality activities** for the **start of production** and **consequently facilitating early launch and stabilization of production.**



1.1 Definition of Terms

1. Production Preparation

Actual preparations carried out in conjunction with necessary planning and the contents of those plans in order to perform production at the current stage and the next stage.

2. Initial Management

Actions intended to stabilize quality under a special management system that integrates the development planning division, manufacturing division and quality assurance division of BIL and manufacturing subsidiaries.

3. Daily Management

Action to ensure thorough application of standards with a focus on manufacturing-related departments of manufacturing subsidiaries in order to maintain the required level of quality in our processes and raise it higher than current levels, following the termination of the initial management of production trial stage.

4. Assembly Trial Session

A meeting in which the R&D department of BIL informs manufacturing related departments of BIL of the requirements for Assembly with regards to product safety and quality.

5. Concurrent Leader for Manufacturing

Leader who coordinates with the product development project leader to arrange relevant work at the manufacturing-related department of BIL.

6. Critical QA Items

Are requirements to assure quality characteristics for production.

① Product Safety
② Safety standards and regulations
③ Quality Assurance

1.1 Definition of Terms

7. Production Trial Preparation Review

To examine whether issues at production design are closed and increased perfectibility of the production design.

8. Standards

Are requirements to assure quality for processes.

9. Managerial Standards

Are criteria whether all requirements from the design department are for sure met or whether in-process 4Ms in each process are maintained or not.

10. Work Standards

Includes in-process 4Ms in order to meet quality requirements for processes.

1.1 Definition of Terms

11. In-process 4Ms

① Operator skills (Men)
② Equipment, Jigs and Inspection Tools (Machines)
③ Work Procedures (Methods)
④ Supplied Parts (Materials)

12. Process Capability

Is a measurable property of a process according to the specification, expressed as a process capability index (e.g.,C_p, or C_{pk}) or as a process performance index (e.g.,P_p, or P_{pk})

13. Abnormality

Is a state of deviation from the normal or difference from the typical (such as work that differs from the specification or sharp drop in defect rates).

1.1 Definition of Terms

14. Stopgap Measures

When an abnormality is found and you can't do the standardized work, stopgap measures are taken to meet the specification.

15. Preventive Measures

Are taken to prevent the recurrence of the problem, to identify the root cause of the abnormality and to update the standards.

16. Tentative Measures

Are taken before taking preventive measures and to meet the demands from the design dept. The procedure for this should be established in advance.

17. Environment-conscious designing

Implementation of the **development design** of products conforming to the R3601, “Environmental Management Regulations”, or the GR3611 “Group Environmental Management Regulations”, product manufacturing equipment design and the production process design to work on the reduction of environmental burdens such as compliance with laws and regulations related to environment, avoidance/reduction of harmful substances, improvement of recycling efficiency, etc.

18. Environment-conscious manufacturing

Implementation of daily **manufacturing management** of products conforming to the R3601, “Environmental Management Regulations”, or the GR3611 “Group Environmental Management Regulations”, to work on the reduction of environmental burdens such as compliance with laws and regulations related to environment, avoidance/reduction of harmful substances, improvement of recycling efficiency, etc.

19. PS Mark

Stands for the Product Safety mark, which is attached on drawings for critical items or instructions regarding safety.

20. Design-in Activities

Activities incorporated into the activities of manufacturing-related departments from upstream processes prior to drawing output, expanding manufacturing related requirements to other divisions and contrived to achieve consistent production.

21. Production Planning

Actions involved in clarifying the following items and planning the specifics of how production will be actualized

21. Production Planning

- Creation of management process tables
- Creation of work instruction sheets
- Assessment of physical ease of assembly
- Review of assembly line composition
- Jig and tool design and creation arrangements
- Equipment creation arrangements
- Equipment installation inspections
- Personnel planning and coordination

22. Auxiliary Materials

Includes parts that accompany completed product to customers as well as packing material as defined in Engineering Standards T0-016.

① Materials attached to completed products

② Materials for packing or shipment

23. Indirect Materials

Are articles on the market other than Auxiliary Materials.

① Materials used to maintain performance but not attached to products.

② Materials used only in the process of verifying the quality of products.

③ Materials used for packing or in-house transportation.

24. Receiving inspection Standard Sheet

Includes inspection methods, items, standards and drawings necessary for incoming inspections.

25. Die Verification

Is the inspection of dies to see whether they meet the design specification of parts.

26. Initial lot parts

Are parts manufactured in the first lot under the designated conditions right after a design has been newly introduced or modified.

27. Limit Samples

Are used as objective criteria to determine whether products meet quality requirements with regards to their appearance or functional departments concerned. As a general rule, these are acceptability criteria. However, if they are used as non-acceptability criteria, that should be clarified in the certification of the limit sample.

28. Limit Sample Management Sheet (hereinafter referred to as LSMS)

Is used to record the history from drafting through fabrication, storage and disposal of limit samples.

29. Limit Sample Certificate

Is a certification with certification seal on it, issued for each limit sample that is certified.

1.1 Definition of Terms

30. Department Limit Sample Management Sheet (hereinafter referred to as DLSMS)

This is used to manage a department's limit samples by recording storage and inspection history.

31. Reference Number

Is the reference number of the LSMS used to refer to DLSMS in conjunction with related to limit samples.

32. LSMS Number

Each LSMS has a serial number

33. Limit Sample Number

Is a serial number to identify multiple identical limit samples.

② Production Preparation in the Preliminary Activity and Preliminary Technical Development Stages

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Hereinafter, this refers to activities related to production preparation, from the start of preliminary activities until prior to the holding of the product strategy meeting.

2.1 Starting Design-in Activities

Whenever a project involves implementing design-in activities, preliminary activities are begun in accordance with the business process described in section 2.1 of these regulations. With the start of these activities, the product strategy plan and outline of quality regarded for the new product must be understood, and collection and analysis of the data needed to start preliminary activities (including benchmark models, competitors' models, problems with previous models, COPQ reduction measures, and next-model improvement requests from the production center) are undertaken. High-level managers in manufacturing-related departments of BIL make requests to related departments for cooperation on the basis of that data.

2.2 Consultation/Consideration in accordance with laws and regulations or outside contracts

Depending on the necessity, the senior managers in charge of manufacturing departments of BIL contact with each related department (departments in charge of laws, environment, PL and intellectual property) regarding the assumed compliance with various laws and regulations or outside contracts in the production activities, and then consulate and discuss about the necessity of compliance (outline/schedule if the respondence is required).

2.3 Setting Manufacturing Targets

The senior manager in charge of the manufacturing department of BIL should establish target values for manufacturing-related items (assembly, equipment, and parts) in accordance with the characteristics of the project. (Examples of items: process count/ST, intermediate materials costs, equipment costs, and so on)

② Production Preparation in the Preliminary Activity and Preliminary Technical Development Stages

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2.4 Setting Preliminary Engineering Development Items and Stretch Goals

The senior manager in charge of the manufacturing department of BIL should establish preliminary engineering development items related to manufacturing as necessary to attain the level of quality needed by the customer. He should also establish the quality targets that need to be met and establish research aims and target levels for each preliminary engineering development item.

2.5 Conceptual Design Review

The conceptual design is understood through DR utilizing 3D data. A high-ranking manager in the manufacturing-related department of BIL then submits improvement proposals to the development planning division and other related divisions with a focus on component reduction, component sharing, work reduction, automation, and component shapes that facilitate quality control more easily. If necessary, assessment of physical ease of assembly, and physical standard time (ST) calculations and analyses are also conducted (mainly for important technology).

2.6 Engineering Trial Review

DR of the actual engineering trial product is carried out, and the following items are implemented.

- Checking if the items proposed during the conceptual design review phase have been reflected in the engineering trial product
- Making improvement proposals based on the DR of the actual product to the development planning division and other related divisions
- Assessment of physical ease of assembly as well as physical standard time (ST) calculations and analyses

In addition, it is necessary to perform verification centered on design improvement portion, such as ease of assembly, static/dynamic interference checks.

2.7 Critical Technology Confirmation

Each preliminary development leader should summarize the results of implementation of preliminary engineering development.

③ Production Preparation at the Performance Trial Stage

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Hereinafter, this refers to tasks related to production preparations, from the kickoff meeting until prior to the holding of the investment approval meeting.

3.1 Appointment of Concurrent Leader for Manufacturing

The manager in charge of manufacturing-related department of BIL should judge the necessity of concurrent leader for manufacturing according to the characteristics and purpose of the project. If judged as necessary, the manager in charge of manufacturing-related department should appoint a concurrent leader for manufacturing when starting the project.

3.2 Setting Manufacturing Targets

The senior manager in charge of manufacturing of BIL sets QCD targets for manufacturing-related items (assembly, equipment, and parts) based on the results of the preliminary engineering development, and he clarifies success guidelines and activity systems. (Examples of items: man-hours/ST, indirect materials costs, equipment costs, and so on)

3.3 Production Equipment Review

The senior manager in charge of manufacturing of BIL draws up a plan for production equipment. For equipment that needs to be ordered in advance, approval of costs and timeframe must be obtained from the business management executive officer of BIL. BIL should introduce and manage equipment in accordance with R3301, “Regulations for Equipment Management,” and R3301-01, “Procedures for Production Equipment Management.”

In addition, manufacturing subsidiaries should also check the equipment introduced by themselves in accordance with the above regulations. In such cases, BIL should disclose the corresponding part of the above regulations and provide guidance to manufacturing subsidiaries as necessary.

③ Production Preparation at the Performance Trial Stage

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3.4 Performance Trial Review

A DR of the actual performance trial product is carried out, and the following items are implemented.

- Checking if the items proposed earlier have been reflected in the performance trial product
- Making observations and identifications from the manufacturing workplace viewpoint (DR by production center members using the actual product, as required)
- Making improvement proposals based on the DR of the actual product to the development planning division and other related divisions
- Carrying out assessments and inspections of manufacturing quality (component quality, process quality, yield, direct-run rate, etc.) and incorporating into the product design countermeasures that deal with identified problem areas
  See GR3406, "Regulation for Parts Quality Control", for more on checking component quality.
- Review of new mechanisms is carried out, and the following items are implemented.

  - Assessment of physical ease of assembly
  - Calculation and analysis of physical standard time (ST)
  - Creation of jig specification sheets
  - Creation of management process tables
  - Creation of a process analysis tree diagram
  - Process time analysis
  - Creation of equipment specification sheets

The items shown above involve participation in the review session for the performance trial. Following the implementation of the performance trial, if any additional confirmation trials come up, the entire set of tasks shown above should be repeated, with a focus on the areas of change.

3.5 Preparation of Production Specifications

The concurrent leader for manufacturing or the manufacturing-related manager compiles and draws up the results of the design-in activities as Production Specifications. Production Specifications are approved in accordance with the "Regulations for Development Management".

③ Production Preparation at the Performance Trial Stage

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3.6 Production Plan Review

The concurrent leader for manufacturing or the manufacturing-related manager shall prepare the following items to discuss at Production Plan Review, and obtain approval from the approver stipulated in the procedure manual for each business. The purpose of Production Plan Review is to discuss the outline of production for a new product.

Items to be discussed

(a) Production quality (quality of parts and processes, yields, and direct-run rates)
(b) Manufacturing engineering (manufacturing and assembly methods, line configurations, and assembly processes)
(c) Production engineering (equipment, dies)
(d) Production planning with regard to products, supplies, and recycled parts (dies, equipment [including internal and external testing plans], start-of-production planning, internal and external product planning, production capacity, and production factories)

* Production plans also include prototype production plans.
* For each item, approval of the division head must be obtained in advance, and Production Plan Review must be involved.

3.7 Checking Reflection Status of Critical Technology Items

Whether or not the technology developed in advance is reflected in the product should be checked. If there are any issues related to critical technology, the measures taken in response should be clarified, and the specifics should be reviewed at the investment approval meeting.

④ Production Preparation at the Product Trial Stage

Hereinafter, this refers to tasks related to production preparation from the investment approval meeting until prior to the merchandizing meeting.

At the investment approval meeting, QCD is finalized and approval is obtained for production plans and equipment ordering plans.

Follow “Regulations for Development Management” for forms for Merchandizing. Product trials and die trials can proceed concurrently in accordance with the project plan. The transition to Die Trial (start of assembling parts produced by dies) should be determined by following the product development procedure manual for each business. Die trial is carried out by assembling the parts produced by the die to find defect of design before production trial. If necessary, please advance it while discussing with relevant departments about evaluation results of each die trial and handling of problems etc.

4.1 Implementation of the Product Trial

(1) Each manufacturing-related manager should, within the scope of product trial implementation, reach an understanding of the required quality-related items shown below, through the product trial assembly explanation session and part quality review session.

For Products	For Parts
• Design Quality Specification	• Part Function
• Trial Drawings (Assembly • Drawings, Part Drawings)	• Trial Part Drawings
• Critical QA Items	• Critical QA Items
• PS Mark	• PS Mark

(2) The process planning manager for the manufacturing assembly process (hereinafter referred to as the product assembly process planning manager) should reach an understanding of the assembly procedure through the product trial assembly explanation session and by implementing assembly.

(3) Each manufacturing-related manager should consult with related divisions on problem areas that are discovered, including those related to safety, performance, assembly, and part workability, as well as the measures to take in response.

(4) The results of the product trail should be compiled, and they should be reflected in the production preparations for the die trial.

④ Production Preparation at the Product Trial Stage

4.2 Implement and confirmation of an environment-conscious designing

(1) The department in charge of purchasing must conduct the environment-conscious response in collaboration with department in charge of development and design departments.

(2) The senior managers of the department in charge of equipment engineering must confirm that there is no adherence of chemical substances contained in products to products by utilizing equipment.

4.3 Production Planning

4.3.1 Production Planning

(1) The senior manager in charge of manufacturing should be given an explanation from the department in charge of development planning with regard to the required quality level. He should then begin production planning for the purpose of maintaining the required quality level and ensuring safe production.
* With regard to parts, it is mainly parts made within the company (e.g. molded parts and circuit boards) that this applies to.

(2) The person in charge of the assembly process design should study assembly workability to make plans for the following:

- Process tree chart planning
- Management method planning
- Operation method planning
- Jig and tool analysis tool planning
- Physical assembly workability assessment
- Physical standard time (ST) calculation and analysis
- Machining time analysis
- Equipment design

④ Production Preparation at the Product Trial Stage

(3) The person in charge of parts engineering must secure the part quality based on GR3406, "Regulations for Part Quality Management" by requesting the consideration of workability to parts processing department and company.
Here are the items to be discussed. (Applicability varies according to the part.)

- Plant Layout, work environment
- Die design
- Machining conditions, measurement procedures
- Process control items and management
- Method, process and machining standards
- Machining equipment, jigs and dedicated inspection tools
- Measurement standards, measurement methods
- Suggestions to design to improve workability and measurement

(4) When using complete products is only way to conduct destruction testing to evaluate quality requirements, the work method, required skills and control method (in particular, traceability) should be carefully considered upon process design. The following are processes subject to consideration

- Adhesion, welding, caulking, press fitting, soldering, heats treatment, surface treatment, paint, washing, and labeling

In order to maintain quality, a certification system should be established for workers, and management requirements should be established for equipment used in these processes.

④ Production Preparation at the Product Trial Stage

(5) In order to meet quality requirements related to safety, such as critical safety items (PS Mark), measures like fool-proofing and double-checking are taken in order to make a plan for work sequences and management methods. In order to stress safety, either the PS Mark is added to the Process Control Sheet or Work Instruction Sheet, or exclusive notices are prepared.

(6) The person in charge of process design has to list all the auxiliary materials used for the line (machining, assembly and packing processes) on the Process Control Sheet and/or Work Instruction Sheet. In the meantime, he has to make sure that none of the lines have a harmful impact due to chemical substances contained in products. The senior manager in charge of development planning should inform the senior manager in charge of materials purchasing of the above auxiliary materials list.

(7) The department in charge of materials purchasing must apply to the code-granting department of BIL for an auxiliary material code when a material is newly introduced Brother-Group-wide. The code-granting department assigns an auxiliary material code and must inform the department in charge of purchasing.

(8) The department in charge of purchasing must deal with the environment-conscious design response regarding the secondary materials specified by the Design Department and the secondary materials used in all processes (machining, assembling, etc.).

④ Production Preparation at the Product Trial Stage

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4.3.2 Planning of Receiving Inspection

The senior manager in charge of parts engineering plans how to do receiving inspection of parts following an explanation of quality requirements from the development and design department. Regarding the method of working for the acceptance inspection, comply with GR3406, “Regulations for Part Quality Management.

4.4 Consideration related to workability of parts

When additional processes of parts in a product assembling process are required, the concurrent leader for manufacturing or the manufacturing-related manager must deal with it in cooperation with senior managers in charge of parts engineering.

4.5 Draft of Production Preparation Plan Document

The concurrent leader of manufacturing or the manufacturing-related manager coordinates the preparation planning for the prepared items in the production designing as a “Production Preparation Plan Document”, and then drafts the plan.

The production preparation plan document includes the action contents as the production preparation and it also summarizes the preparation situation before the start of each prototype trial by the stage, and it shall be approved in accordance, “Regulations for Development Management”.

④ Production Preparation at the Product Trial Stage

【Discussion contents】
(a) Quality evaluation based on the customer quality standards, Measures against problems and the verification methods
(b) The full-scale production plan (start-up planning and procurement planning) regarding machine units/supplies/recycled products
(c) Additional mold response plan
(d) Facility reinforcement plan
(e)Handling of prototypes
(Prototypes that the sample shipment is required under the approval by the business management executive officer of BIL will be included.)

Furthermore, when starting a mold prototype trial, create the plan documents before the mold prototype trial if necessary, and then complete the approval.

4.6 Implementation of Production Plan Checks and Die Production Preparation
(1) The senior manager in charge of manufacturing or the manufacturing-related manager should implement a check of the implemented production plan details.
(2) When starting a mold trial, the concurrent leader of manufacturing summarizes the action contents as the mold prototype preparation in the product preparation plan document if necessary.
(3) When carrying out a die trial, it is necessary to implement the following items based on the information from (1) and the die trial plan (date, specifications, quantity, etc.).
In addition, the concurrent leader for manufacturing or the manufacturing-related manager should hold a Die Preparation Status Review Session after Design Quality Verification Result Session to implement deliberation on the preparation status of die trial by the manager in charge of manufacturing-related department of BIL.

- Creation of the management process table
- Creation of a work instruction sheet
- Jig and tool design and manufacturing arrangements
- Review of the assembly line configuration
- Equipment manufacturing arrangements
- Personnel planning and coordination

④ Production Preparation at the Product Trial Stage

When adding a die trial stage that wasn't part of the original plan, (2) above should be carried out again with regard to the additional portions, and members on equal footing with the members making up the die trial preparation status review session should be convened to discuss the matter.

4.7 Implementation of Die Trial

(1) The department in charge of manufacturing should identify problems through the implementation of a die trial. Additionally, it should implement a performance assessment of prototype product to identify performance-related problems. If problems are identified, it is necessary to discuss response measures with related departments.

(2) An assessment and inspection of manufacturing quality (including part quality, process quality, yield, and first-run rate) should be implemented, and responses to any problems identified should be incorporated into the production plan. When this is done, revert back to the targets decided upon in the manufacturing specification sheet, and perform a reexamination of the manufacturing specification sheet if there is any difference in how the target values are to be achieved. (* This is not to be done for changes to committed target values.) When performing a reexamination of the manufacturing specification sheet, it should be finally determined before Production Trial Preparation Review is held.

(3) The results of the die trial should be compiled, and they should be reflected in the production plans for the production trial.

④ Production Preparation at the Product Trial Stage

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4.8 Implementation of Production Trial Preparations

The following items should be implemented based on the results of the die trial and the production trial plan (date, specifications, quantity, etc.).

- Creation of management process tables
- Creation of work instruction sheets
- Jig and tool design and manufacturing arrangements
- Assembly line configuration inspection
- Equipment manufacturing arrangements
- Equipment installation inspections
- Personnel planning and coordination

4.9 Production Trial Preparation Review

(1) The concurrent leader for manufacturing or the manufacturing-related manager should prepare for the production trial by compiling the implemented items as production preparation plans.

(2) The concurrent leader for manufacturing or the manufacturing-related manager should convene the Production Trial Preparation Review and perform a review of the production trial plan, production trial preparation status, production equipment preparation status, die increase response plans, and obtain approval from the approver stipulated in the procedure manual of each business.

④ Production Preparation at the Product Trial Stage

(3) The senior manager in charge of manufacturing should prepare the following documents as the need arises. It is even more efficient to circulate the documents within the departments concerned.
   a. Changes agreed upon at the Assembly Trial Session and Part Quality Review Session A regarding the Critical QA Items List
   b. Process Analysis Tree Chart, in order to clarify processes
   c. Process Control Chart, in order to clarify progress and control methods
   d. Documents needed in order to clarify jobs in processes
   e. Other documents that the senior manager in charge of manufacturing requires for examination at the Production Trial Preparation Review (illustrations of fixtures and inspection tools)

(4) The senior manager in charge of parts engineering should prepare the following documents as the need arises. It is even more efficient to circulate the documents within the departments concerned.
   a. Changes agreed upon at the Part Quality Review Session regarding the Critical QA Items List
   b. Documents needed in order to clarify inspections, including inspection items, method and tools regarding the Critical QA Items

If the concurrent leader for manufacturing or the manufacturing-related manager needs more information, he may ask the responsible department to prepare for examination at the Production Trial Preparation Review.

④ Production Preparation at the Product Trial Stage

4.10 Production Trial Preparations

(1) The senior manager in charge of manufacturing of BIL should appoint jobs for preparations for each process to appropriate persons after production drawings are released in order to complete production trial preparations by the due date. The following jobs should be done by each person in charge of process preparation.

<u>Items for Assembly</u>

Equipment
- Arrangement and inspection of assembling equipment, conveyers and fixtures
- Arrangement of dedicated and general inspection devices
- Layout of lines and auxiliary equipment

Standards
- Preparation of Managerial Standards
- Preparation of Work Standards (Work Instruction Sheet)

Workers
- Arrangements for staffing
- Providing training and practice

Parts
- Procurement of parts for production trials

<u>Items for Machining</u>

Equipment
- Arrangement and inspection of machining equipment, conveyers and fixtures
- Arrangement of dedicated and general inspection devices
- Arrangement and verification of Dies

④ Production Preparation at the Product Trial Stage

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	• Layout of machining lines and auxiliary equipment
Standards	• Preparation of Managerial Standards
	• Preparation of Work Standards (Work Instruction Sheet)
Workers	• Arrangements for staffing
	• Providing training and practice
Materials	• Procurement of material for machining

Items for Inspection

Equipment	• Arrangement of dedicated and general inspection devices
Workers	• Arrangements for staffing
	• Providing training and practice
Standards	• Preparation of Inspection Standards (Receiving Inspection Standard Sheet)

Refer to Engineering Standards T0-061, “Standards for Process Control Sheets”, and Appendix 7 for preparation of the Work Instruction Sheet.
The preparation of Work Instruction Sheet is specified in the technology standards separately.

(2) The senior manager in charge of parts engineering should audit the processes for machining and verify dies, inspect parts to grasp the quality of delivered parts, and carry out response measures.

(3) Refer to Appendix 6 for the preparation of limit samples (criteria) for production trials and full-scale production.

⑤ Production Preparation at the Production Trial Stage

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Hereinafter, this refers to tasks related to production preparation from the commercialization approval meeting until prior to the production sales meeting.

At the commercialization approval meeting, reports are given on the status of preparations for the production trial, and approval for moving to the production trial stage is obtained. Refer to “Regulations for Development Management” for forms for gaining approval by the time of the production sales meeting. If necessary, please advance it while discussing with relevant departments about evaluation results of each production trial and handling of problems etc.

(1) The manufacturing-related department of BIL or the manufacturing subsidiary proceeds with trials (assembly and machining) under the same conditions to the full-scale production.
(2) Based on GR3402-04, “Procedures for Management of Chemical Substances Contained in Products”, the department in charge of purchasing and the senior managers of the department responsible for the judgment of chemical substances contained in products must deal with the environment-conscious response.
(3) The quality assurance department or the department in charge of manufacturing of BIL, or the manufacturing subsidiary must check if all items and management methods related to safety (safety-related Critical QA Items, PS marks, etc.) have been developed. After the Production Trial, whether safety-related standards are thoroughly complemented and whether they are effective should be assessed. If the standards are not satisfactory, they are to be updated.

⑤ Production Preparation at the Production Trial Stage

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5.1 Implementation of the Production Trial

(1) The manufacturing-related department of BIL or the manufacturing subsidiary should proceed with trials (assembly and machining) under the same conditions as full-scale production.
(2) Each senior manager should conduct an evaluation of the products from the production trial. Any problems related to process capability (e.g. insufficient capability), assembly, or equipment, as well as any problems that occur in individual products or parts during assembly of production trial products should be entered on the issue list. Each senior manager should also implement an assessment and inspection of product quality (part quality, process quality, yield, and direct run rate) with regard to production, and have the results be reflected in the production preparation plan.
(3) The concurrent leader for manufacturing or the manufacturing-related manager should check the effectiveness of responses taken toward all problems on the issue list by the time Production Preparation Review is convened.

5.2 Initial Management

The senior manager in charge of manufacturing of BIL or the manufacturing subsidiary should draw a plan of Initial Management by the time Production Trial for assembly and machining starts to establish a system to detect abnormality early and solve them. Each senior manager should continue the Initial Management if that is not terminated by the start of production. That is referred to as Initial Management of SOP (Start of Production) and the procedures are the same as the original one. The senior manager in charge of manufacturing of BIL or the manufacturing subsidiary assesses all the items according to PS mark standards. The number of parts subject to inspection should be in advance determined.

⑤ Production Preparation at the Production Trial Stage

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5.2.1 Planning of Initial Management

(1) The senior manager in charge of manufacturing of BIL or the manufacturing subsidiary should select items subject to initial management from process control items in the managerial standards to draw a plan by the time when the Assembly Trial starts.

(2) The concurrent leader for manufacturing or the manufacturing-related manager establishes the following concrete targets for initial management, instruct each department about them and perform progress management.

Examples of initial management items

- Defect ratio based on product inspection from the quality assurance department
- Defect ratio of final process
- Actual working hours including irregular works to meet quality requirements
- Initial unstable period

5.2.2 Implementation of Initial Management

The senior manager in charge of manufacturing of BIL or the manufacturing subsidiary should conduct initial management for assembly and machining in order to evaluate process capabilities and whether safety is ensured.

⑥ Production

This refers to tasks related to production following the production sales meeting.

At the production sales meeting, reports on production preparation status are given and discussed.

The senior manager in charge of manufacturing of BIL or the manufacturing subsidiary prepares work responsibility charts (including names of supervisors, persons in charge, and process charts), develops quality indicators to ascertain production status, and proceeds with daily management. For more information on daily management, refer to BIL GR3407, "Regulation for Production Daily Control Management".

6.1 Implementation and confirmation of an environment-conscious manufacturing

The department in charge of the acceptance inspection of BIL or manufacturing subsidiaries must deal with the environment-conscious manufacturing based on GR3404, "Procedures for Management of Chemical Substances Contained in Products" of the company regulations, etc.

6.2 Shipment

At the shipment judgment meeting, reports on the results of quality assessment for products and the status of production implementation are given, and product shipment is discussed.

6.2.1 Shipment of Initial Parts

(1) Refer to the "Regulations for Development Management" for shipment of initial parts. The inspection prior to shipment must be performed in accordance with the environment-conscious manufacturing.

(2) Regarding the inspection prior to shipment, make sure to follow GR3402-04, "Procedures for Management of Chemical Substances Contained in Products" of the company regulations, etc.
(3) The department in charge of quality assurance and the department in charge of manufacturing of BIL, and the manufacturing subsidiary should assess whether or not safety standards (safety-related critical safety items and PS marks) are being precisely and effectively observed.
(4) The manufacturing-related department of BIL or the manufacturing subsidiary should record the result of the shipment judgment regarding product safety and the results of applying those results to PS mark manufacturing.

6.2.2 Regular Shipments

(1) The department in charge of manufacturing and the supervisors of the manufacturing processes should inspect and verify completed products in order to ship only acceptable products.
(2) The decision to make a shipment related to chemical substances contained in products must be handled in accordance with GR3402-04, "Procedures for Management of Chemical Substances Contained in Products".
(3) Each executive officer in charge of business management of BIL should assume responsibility for shipping accepted products. The approved person in charge should assume responsibility of regular shipments.
(4) The department in charge of quality assurance, the department in charge of manufacturing, and the supervisors of the manufacturing processes should evaluate whether daily routines such as safety standards are effectively followed. How to diagnose that is left to the discretion of each business domain.

⑦ Handling for Changes Related to Product Safety

brother at your side

This chapter explains handling for changes related to product safety (design changes or update of standards) for production at BIL. As needed, jobs described in chapter 7, "Handling for Changes related to Product Safety", are subcontracted to subsidiaries with certain instructions.

7.1 Revision of Designs and Standards

7.1.1 Design Changes Related to the PS Mark

(1) When the design is changed related to PS mark (including additions, update of standards such as 4M, The department in charge of development design shall investigate whether that is reasonable.

(2) As the need arises, departments in charge of development design and quality assurance evaluate further product safety risks (including abnormality tests) under real environment conditions.

(3) When the test is run, departments in charge of development design and quality assurance confirm safety based on the written results and gain approval from the quality assurance general manager. After the approval, the development design department issues design change instructions.

Example revisions related to PS marks: Changes in material, insulation and substrate elements

⑦ Handling for Changes Related to Product Safety

7.1.2 Update of Standards Related to PS Mark

* E.g.: Changes in equipment, suppliers and methods (of machining and assembly)

(1) When standards related to PS marks are updated, the manufacturing-related departments, the quality assurance department, and the supervisors of the manufacturing processes should discuss whether safety evaluation is needed. The development design department may join if the need arises.

(2) When the evaluation is needed, machines and parts are subject to the evaluation (including abnormality tests).

(3) When the evaluation has been conducted and the result turns out that the actual machines and parts are satisfactory, the manufacturing-related departments, the quality assurance department, and the supervisors of the manufacturing processes must prepare a report on the results in order to gain approval from the quality assurance general manager.

(4) When some follow-ups are required at the production line, the production department updates their standards and informs everyone concerned to adhere to it.

⑧ Checking Target Attainment Results

In order to facilitate the following projects, the senior manager of the department in charge of manufacturing of BIL should check the attainment results for each target written down in the manufacturing specifications.

THANK YOU!