PROCESS DESIGN QUALIFICATION

Procedure: 4-Pr-007	Version: 39	Page: 1/14	4-PR-007/39

I. Purpose

This procedure provides guidelines responsibility for controlling of process design qualification for new products transferring from FJK/ Customer to FOV or internal transfering between sections in FOV, supplier changing and change control.

And, this guidance outlines the procedure of monitoring and measuring the characteristics of the product.

II. Application

1. This procedure is applied to all type of products have been qualified by customer or FOV design section follow to: 8-Pr-0001.
2. This procedure concerns to all sections in FOV.

III. Reference documents:

1. 0-QEM-001: Quality and Environmental Manual

IV. Term definition:

PIC: **P**erson **I**n **C**harge

DR: **D**esign **R**eview

QC: **Q**uality **C**ontrol

OP: **O**peration **P**rocedure

PQ: Process qualification

4M are:
- **M**an
- **M**achine; Tool; Jig
- **M**ethod (including related documents)
- **M**aterial

IQ: **I**nstallation **Q**ualification

OQ: **O**peration **Q**ualification

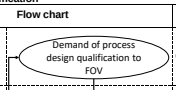
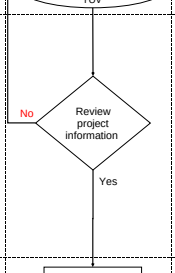
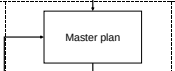
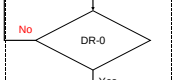
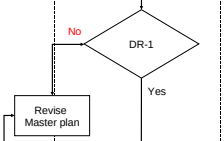
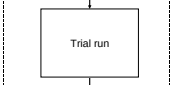
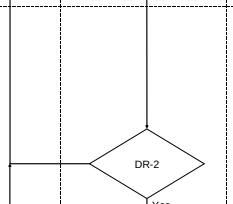
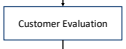
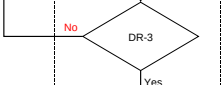
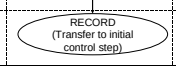
PQ: **P**rocess **Q**ualification

Q-Condition: Quality Conditions to assure good product's quality and safety for operators. It's including condition of 4M and E of process.

MSA: **M**easurement **S**ystem **A**nalysis

V. Content:

A - Process design qualification

Step	Flow chart	All concerned section	Description	Relative document/Record
1		Customer 3B	+ New product transfering from customer apply follow this procedure. + Transfering manufacturing production line between diffirent factories in FJK group of company also follow this procedure.	
2		MDP/ PRE/ QAE	+ Manufacturing division manager will asign the project belong to which PRE sections. The PRE section manager will asign project leader for this project to review Input - Product specification or purchase specification. - Bill of materials - Forecast & market - Machine & equipment list and critical spare parts (if any) - Workshop & facility requirement: space areas, environmental (temperature, Humidity, particle, ESD…), gas, water, lighting,… - Referent production data for bench mark such as: first yield, final yield, productivity, Cpk... - Any needs of manpower arrangement (basic knowledge) and/ or specific training such as On job training & qualifying. - All relative quality documentation, others the requirement from Customer and production data (if any). - PIC review special affect to environment from operation, material, or product that out significant aspects of company.	
3		Project leader	+ Concerned sections asign PIC to join the project. + Project leader make Master Plan and get confirmed by his/her manager. Then the master plan shall be informed to all concerned sections. + Note: all DR meeting must be joined and consulted by at least one executive position upward.	+ Form: 4-Pr-007-4-Fo-0003 Master Plan.
4		All concern sections	+ DR-0 to share all information of project, assigned PIC of each relative sections, setup target & finalized the Master Plan (if any) Input - Share all informations as step 2 of project to concerned PIC - Review the Master Plan. - Discuss & setup the target about QCD for production line. Output - Finalize master plan with target QCD, - Result of confirmation with customer what kind of property and document can be disclosed with outside (supplier, subcontractor, visitor) if any. - DR-0 meeting minutes	+ Form: 4-Pr-007-4-Fo-0004 meeting minutes
5		All concern sections Project leader to revise plan (if any)	+ DR-1: to review 4M preparation before Trial run Input: - Customer specification - WI or FMEA from customer if any - Other requirements - Draft QC Flow - DR-0 meeting minute Review in DR-1 - List out requirements from specification and other requirements into customer requirement break down sheet - Review detail requirement with content of draft version of QC flow chart, Operation procedure, FMEA and PS - Confirm progress of Machine, Line layout, Material preparation and Manpower arrangement. - Review status of action items in DR-0 Output: - Finish checking draft version of QC flow chart, OP, FMEA, PS, Check sheet and concerning document for trial run - Finish review 4M for trial run - Issue Trial run plan - Define which process need to run PQ, following Appendix A-Process qualification requirement, and is documented in QC flowchart - Define which measuring process need to apply MSA, refer to Appendix E-MSA requirement - DR-1 meeting minutes + In case the preparation can not finish on time, the team shall re-consider to postpone the DR-1 or not and revise Master Plan again if any. The project leader shall update & send latest updated Master Plan to the all concerns.	+ Form: 4-Pr-007-4-Fo-0005 Customer requirement break down sheet + Form: 4-Pr-007-4-Fo-0002 Trial run request. + Refer to MSA flow chart in 5-Pr-007 Equipment control activities + Form: 4-Pr-007-4-Fo-0004 meeting minutes
6		All concern sections	+ Trial run: to evaluate effectiveness of process design, process control and training operator. Input: - Trial run plan - Quality document: OP, QC, FMEA, PS, check sheet, template. - DR-1 meeting minutes Review during Trial run - Process productivity, Process yield ratio, Process trouble - Machine, tool jig accuracy and reliability. - Risk from storage, transport, handling material and product - Risk from processing, inspection and packing design method - Evaluate opertor's operation and skill Note: In urgent cases, trial run period can be accepted to use temporary tool, jig approved by executive upward. Output - Confirm actual process compliance with process specification and concerning quality documents - Production data: Yield, Productivity, defect ratio of material… - Machine, tool jig performance: data record on daily check sheet - Product data follow customer and internal requirement: correct and enough data - Training record.	+ Training record: 1-Pr-008-1-Fo-0009
7		All concern sections	+ DR-2: to evaluate variance between the result and the target, review Q-condition & review product compliance Input: - Review the target achievement of trial run. - Record all requirements had been reviewed to "Customer requirement break down sheet". - Production data: Yield, Productivity, defect ratio of material… - Machine, tool jig performance: data record on daily check sheet. - Product data follow customer and interal requirement: correct and enough data. Review in DR2 - Analysis data during trial run in Technical Report - Review the result of trial run compare with target setup in DR-0 step. - Review concerned items implemented from Customer requirement break down sheet to confirm product compliance - Evaluate risk to setup Q-condition & set counter spec (if any). - Consider the impact to cost and delivery - Review draft QC flow chart, Operation procedure, FMEA, PS with customer requirement and actual trial run Output - Confirm product compliance with all requirements - Update quality document (QC flow chart, Operation procedure, FMEA, PS) - Confirm process capacity to prepare Machine and Man for mass production - DR2 meeting minutes	+ Form: 4-Pr-007-4-Fo-0006 Technical report. + Form: 4-Pr-007-4-Fo-0004 meeting minutes
8		Project leader	+ Trial product will be shipped to customer for qualification if requirements. + Customer will qualify and feed back the result.	
9		All concern sections	+ DR-3: to re-view customer evaluation (if any) and to have final conclusion to approve for mass production. Input: - Customer evaluation result - or FOV internal evaluation result - Other request in DR2 Review in DR3 - In case the result of evaluation of New Product is failure, it should return back DR-1 for review & trial run again if any. - Review all quality documents (QC flow chart, Operation procedure, FMEA, PS) before approval for mass production. - Training center confirm all training record must be completed before mass production. - Review the request in DR2 Output - Official quality documents (official QC flow chart, Operation procedure, FMEA, PS) release - Section manager upwards will make final decision to approve for new mass production. - DR3 meeting minutes	+ Update 4-Pr-007-4-Fo-0002: Trial run request. + Form: 4-Pr-007-4-Fo-0004 meeting minutes
10		Project leader	+ Project leader keep the record of design review processes. + The next step follows initial control procedure 4-PR-013	+ Close 4-Pr-007-4-Fo-0002: Trial run request.

PROCESS DESIGN QUALIFICATION

B- Process qualification (PQ)

Step	Customer	Section In charge: Production Engineering	Section In charge: All concerned sections	Description	Relative document/Record
1		PQ demand		- PRE/ QAE engineer will take responsibility to prepare detail plan for IQ-OQ-PQ	- Refer to: 4-Pr-007-4-Fo-0009 PQ implementation
2		Protocol development		- Establish detailed protocols and provide criteria for performing process qualification. + The protocols can make by FOV or base on customer's requirements.	- Refer to: 4-Pr-007-4-Fo-0009 PQ implementation
3		Protocol approval (No / Yes)		- The protocol shall be approved by section manager & manufacturing department manager upwards. - In case customer request for PQ, the protocol will be approved by customer (for both new or modified protocol).	- Refer to: 4-Pr-007-4-Fo-0009 PQ implementation
4		IQ- OQ		- Make IQ-OQ	- Refer to procedure 5-Pr-007 Equipment Control Activities
5		PQ		- Process qualification (PQ) considerations include: (1) Process condition (2) Process criteria (3) Machine/ Jig reliability (4) Special requirement from customer (if any)	
6		Process Qualification report		- PRE/ QAE engineer shall summarize, analyze data and make an technical report for PQ - Process and product data should be analyzed to determine what the normal range of variation is for the process output - Confirm product sample compliance with all requirements - PRE/QAE engineer shall confirm PQ report to concerned members	- Refer to 4-Pr-007-4-Fo-0006 Technical Report
7		Internal Approval (No / Yes); Need Customer Approval (Yes / No); Customer Approval (No / Yes)		- Section Manager upwards will check and approve test result of process qualification - Manufacturing department manager upwards will check and approve process qualification - In case, customer request PQ, we will submit PQ report to customer for approval - In case, the result of process qualification is not good enough or customer need more data from product qualification. Section in charge will consider to make re-verification	- Refer to 4-Pr-007-4-Fo-0006 Technical Report - Refer to: 4-Pr-007-4-Fo-0009 PQ implementation
8		Record		- Delivery the approved report to all concerned - Save for record and close.	

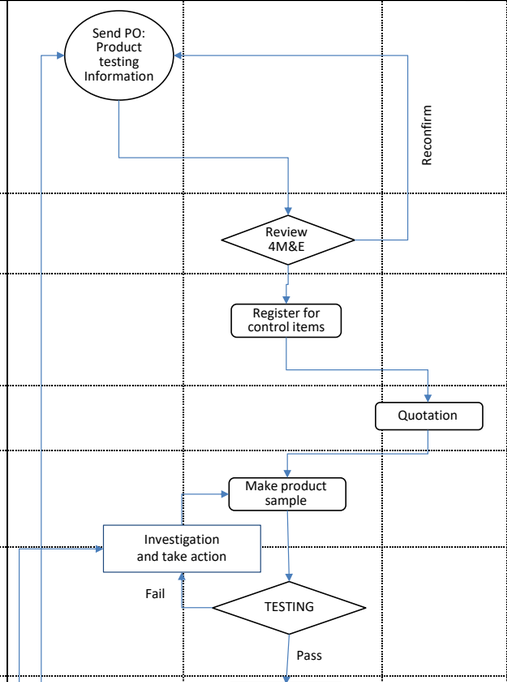
C - PERIODICAL RELIABILITY TEST

Step	Customer	Section In charge: Production engineering	Section In charge: All concerned sections	Description	Relative document/Record
1		Define Product group need periodical reliability test		- Yearly, PRE & QAE engineer will determine the product group need to periodical reliability test . - Define which product group need to periodical reliability test, following appendix B	
2		Request for periodical reliability test		Note: If FJK carry out periodical test by themselves, FOV will use those periodical results.	- Refer : 4-Pr-007-4-Fo-0010 Periodical reliability test request - Refer : 4-Pr-007-4-Fo-0011 Master plan for periodical reliability test
3		Confirmation and approval (No / Yes)		- Section Manager & Manufacturing Department Manager up will review and approve for " Periodical reliability test request " - Section Manager will review and approve for " Master plan for periodical reliability test "	- Refer : 4-Pr-007-4-Fo-0010 Periodical reliability test request - Refer : 4-Pr-007-4-Fo-0011 Master plan for periodical reliability test
4		Testing		- Testing shall be carried out by FOV or outside	- Refer 4-PR-007-4-WI-0002 Guideline for periodical reliability test
5		Test Report (No → NG case follow Control of nonconforming procedure / Yes)		- Test report should summarize with the results. It should derive conclusions regarding the requirement specification. The final report should be reviewed and approved by appropriate management. - In case of the result is not meet requirement: + Follow control of nonconforming procedure, it is necessary to investigate to find root cause. + Must report to BOM to confirm whether this fail of test result should report to customer or not.	- Refer 4-PR-007-4-FO-0006 Technical report - Refer 9-Pr-008 Control of Nonconforming
6		Record		- Delivery the approved report to all concerned - Save for record and close.	

D - CONTROL LONG TIME RE-RUN PRODUCT

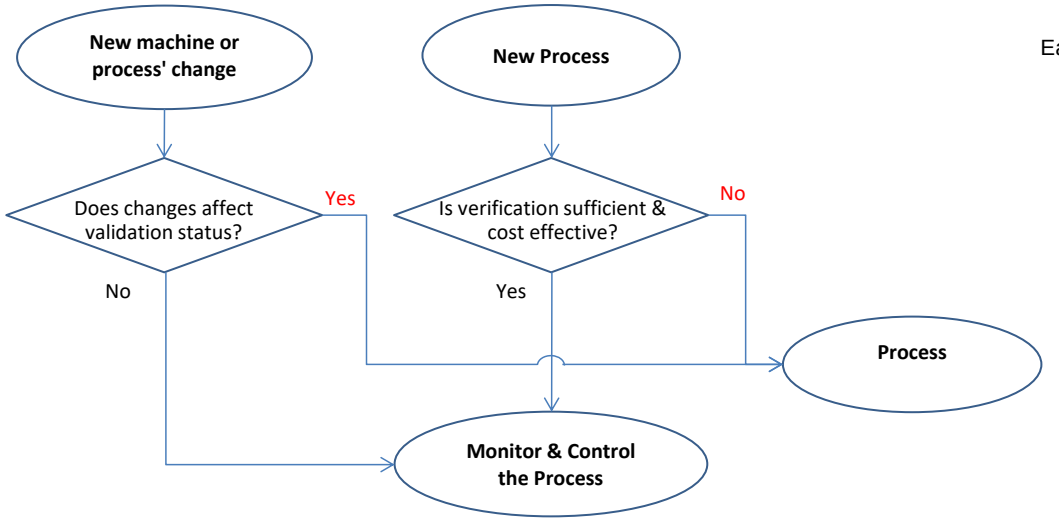
Step	Section In charge: Planer	Section In charge: All concern sections	Description	Relative document/Record
1	Import PO		- Planner import PO to QAD	
2	Less than 6 months: Check Manufacture status (Over 6 months)		- System will check manufacture status at the begin of each day if product has product specification that not run over 6 months	
3	Yes: Check Simple/Similar spec list (No)		- Group leader up will decide what product specification belong Simple/Similar spec list (simple products or similar with product usually running, not require special method) - System will alert to PRE, PRD and QAE section if product has product specification that not run over 6 months and not belong Simple/Similar spec list	+ System will check and inform to PIC by automatic e-mail + Simple/Similar spec list was record at: E-request program: "ALL-Simple/Similar spec list"
4		Review 4M	- Engineer: will review and input action *4M review by E-request program: "ALL-4M Review for Product" or by form 4M review for product long time re-run. Note: Soft "ALL-4M Review for Product" design follow form 4M review for product long time re-run. If want to revise soft, we need to revise this form first.* - Group Leader: follow up 4M review deployment * Depend on the change of 4M, Engineer can request trial run or apply initial control (if necessary)	+ Refer to 4-Pr-007-4-Fo-0012: 4M Review for product long time re-run. Or E-request program: "ALL-4M Review for Product"
5		NG: Check and issue 4M review to concerned PIC (Good)	- Group Leader: check and approve If Not meet requirement, comment and return to Engineer for re-issue - Engineer: issue 4M review to concerned PIC and follow up the implementation	+ Refer to 4-Pr-007-4-Fo-0012: 4M Review for product long time re-run. Or E-request program: "ALL-4M Review for Product"
6		Confirm the result and approve (NG / Good)	- Group Leader: confirm the result * If some actions pending but not affect to quality or function, it could be accepted to start production - Section manager: check and approve to proceed manufacturing	+ Refer to 4-Pr-007-4-Fo-0012: 4M Review for product long time re-run. Or E-request program: "ALL-4M Review for Product"
7		Proceed to Manufacturing		

E. TESTING PRODUCTS (Technical Service_TS)

Step	TS Flow Chart (In charge: Customer / Engineer / Planning / Logistic)	Responsible	Description	
1		Engineer up	FOV receive PO and WD or Information for testing from customer. (1) As for Product testing Information, the critical items must be collected by production engineer as list below a. Specification, including: product specification, materials specification, sensitive machine requirement, packing & test report requirement. b. Internal standard concerns, International standard concerns, Statutory and regulatory requirements (EHS, Law, etc.) c. Bill of materials and list of machine, tool, equipment. d. Process spec., process flow, and working instruction. (2) Engineer up shall hold a meeting with all concern people to make products Engineer up reviewed and break down Customer's request and feedback to Customer to make clear (if any)	Control of External Document: 0-PR-001 Design Review sheet, Form: 8-Pr-0001-8-Fo-0001 Minute meeting report: free format Design Review sheet, Form: 8-Pr-0001-8-Fo-0001
2		Engineer and concerned sections	Review for the Product testing Information: (1) Engineer have to review and feedback 4M and available testing equipments (testing conditions, available machine, during data or not,…). (2) Issue request for purchasing new materials (if any).	Design Review sheet, Form: 8-Pr-0001-8-Fo-0001
3		Engineer, PRD	Register for control items into system: (1) Register new materials code into MFG/Pro database (if any) (2) Choose Work center, Cost center:, allocate into Work center, Cost cente TSA if using for testing purpose. (3) Create PS (if any), make new WI/WD (if any). (4) Define MH for testing (Indirect, direct) and PC rate type (PRE/PRD) Note: (1,2,3): PRE (4) PRE and Concerned sections	Purchasing procedure: 6-PR-002
4		Planner	Planner will issue quotation & send to customer	Product quotation calculation: 000-5-WI-0454
5		Engineer	Product samplings are assembled following customer requirements (quantities, method, material,…) Customer and Engineer investiagate together and confirm nex actions	
6		Engineer	Sample producta are measured & inspection base on Customer requirements: function test, performance test and reliability test for critical parameters. Incase fialed, Engineer communicates to Customer for investiagation	
7		Engineer	Issue one Result Technical testing Report (if any) If test report, QAE need to issue (if any)	Format of Result testing Report: free format
8		Chief up	To ensure all customer requirements was input. To reconfirm the results of the result testing performance and all requirements were carried our properly	Minute meeting report: free format Technical Report: free format Design Review sheet, Form: 8-Pr-0001-8-Fo-0001
9		Customer FJK group	Ship quantity product sample to customer follow inquiry (if any). In case customer not require, can skip this step.	Approval confirmation via email/ meeting/ else…...
10		Engineer	Follow up shipment	

Appendix A: Process qualification requirement

The following work flow to use in determining whether or not a process should be qualified



Each process should have a specification describing both the process parameters and the output desired

When do we need to qualify a process

- Customer's request.
- Where the results of a process cannot be verified by subsequent inspection and test.

When do we need to re-qualify a process

- Apply new equipment or significant change to process which is decided process qualification, the process should be evaludated to determine the affects and the extent of re-qualification considered.

Appendix B: Define priority for periodical reliability test

Table 1. Define priority for periodical test

No	Item	Periodical test			Reference document
		1st priority	2nd priority	Conclusion	
1	Product in test	Follow customer request	Risk assessment (FOV standard)	FOV will follow priority of periodical test yearly	4-PR-007-4-WI-0002 Guideline for periodical reliability test

Note: Secion in charge will review periodical test plan every year.
The periodical reliability test should be performed at least 1 time per 2 years.

*** Set up risk assessment base on cost (sale amount & output) and quality (total defect & major defect)**

Table 2. Ave Sale amount level (S)

No	Ave Sale amount (K.USD/ Month)	score
1	< 300	1
2	≥ 300 ÷ < 800	2
3	≥ 800	3

Table 3. Ave Output quantity (O)

No	Ave output/ month (set/ Month)	score
1	< 10,000	1
2	≥ 10,000 ÷ < 50,000	2
3	≥ 50,000	3

Note: SIC will take Ave monthly sale amount & output of product group in test from last fiscal year (from Apr to Mar).
We assess sale amount (S) and output (O) as paremeter for cost and convert S x O to "C" value as below:

Table 4. Distribute & rule score for S x O to C

O \ S	1	2	3
1	1	2	3
2	2	4	6
3	3	6	9

Convert score for S x O to C

Distribute area	Score
	1
	2
	3

Table 5. Total defect ratio levels (D)

Base on total defect ratio of product

No	Total defect ratio (ppm)	score
1	< 10,000	1
2	≥ 10,000 ÷ <100,000	2
3	≥ 100,000 ÷ <200,000	3
4	≥ 200,000 ÷ <400,000	4
5	≥ 400,000 ppm	5

Note SIC will take Ave monthly defect ratio of product group in test from last fiscal year (from Apr to Mar).

Table 6. Major defect ratio levels (MD)

Base on fiber broken at assembly process

No	Ave Defect ratio (ppm)	score
1	< 1,000	1
2	≥ 1,000 ÷ <5,000	2
3	≥ 5,000 ÷ <10,000	3
4	≥ 10,000 ÷ <20,000	4
5	≥ 20,000	5

Table 7. Decision for periodical reliability test base on risk assessment (R= Cx Dx MD)

C x D / MD	1	2	3	4	5	6	8	9	10	12	15
1	1	2	3	4	5	6	8	9	10	12	15
2	2	4	6	8	10	12	16	18	20	24	30
3	3	6	9	12	15	18	24	27	30	36	45
4	4	8	12	16	20	24	32	36	40	48	60
5	5	10	15	20	25	30	40	45	50	60	75

Requirement for periodical reliability test base on risk assessment

No	Risk assessment (R= Cx Dx MD)	Reliability test (time/ year)
1	1 ÷ 9	1 time/ 2 years
2	10 ÷ 48	1 time / 1 year
3	50 ÷ 75	1 time / 0.5 year

Appendix C: 4M Review for product long time re-run

Review 4M by E-request program: "ALL-4M Review for Product"

***Input information:**

Product:

Current spec version:

New spec version:

***The main information of reviewing:**

Review Material

Review Method

Review Machine

Review Man

Consider apply Trial run plan or Initial control after review 4M

Appendix D: Identify special spec and simple/similar spec

Note: Simple/Similar spec is the spec of simple products or similar with product usually running, not require special method, so we no need to review 4M if product re-run

Special spec is the spec require special method, need to review 4M if product re-run for a long time

Detail identify special spec and simple/similar spec:

Line	Special spec	Simple/Similar spec
Connector	- Drop Cable with Connector - Black Cable product with taro Cable jacket (PNJHG-3846-25-01) - IDM cable with cord 1.1mm	All remain spec
Module	All remain spec	- IDM, NF, S8D, DC product '- Module FSC series
FA	N/A	All spec
MPO	- MPO Pigtail - MPO Jumper - MPO Fan-out	All remain spec
Cleaner	N/A	All spec
Closure	All spec	N/A
Panda	All spec	N/A
FAU	All spec	N/A
3C	All spec	N/A
Coupler	All spec	N/A
Cavity FG	All spec	N/A
Fiber Laser	All spec	N/A
Sensor FBG	All spec	N/A

Appendix G: MSA requirement

The following the requirement to use in determining whether or not a measurement system should be applied MSA

* **When do we need to apply MSA**
  - Customer's request.
  - Severity of measurement result (SMR) effect to product's main function follow table 1, table 2.

- Table1. Severity level of measurement result on product's main function

No.	Severity level	Severity level of measurement result to product quality	Score
1	Negligible	Inconvenience or temporary discomfort but no relevant effect on reliability	**1**
2	Minor	Reduce performance level, (primary function is still OK).	**2**
3	Major	Reduce primary function	**3**
4	Serious	Causes loss of primary function	**4**
5	Critical	Product becomes inoperative	**5**

- Table 2. MSA application for new measurement system

No.	**Severity score**	**needed MSA**
1	≥4	Yes
2	< 4	Not apply

* **MSA will be carry out again if appling any change the main part of system, others MSA will be carry out in yearly**

V. Record:

No.	Record	Responsible for keeping	Retention time
1	Check sheet inspecting in Production, Incoming	Production, Logistic (WH)	Refer to 0-PR-004 Control of Records
2	Test report Check sheet inspecting of product in QA	Quality engineering	
3	New product Trial Run Request Change control request Master Plan Minute meeting report Technical Report Process Validation request and record	Production engineering Quality engineering	

VI. Attached form:

1. FORM: 4-Pr-007-4-Fo-0001 Sparepart list preparation
2. FORM: 4-Pr-007-4-Fo-0002 Trial run request
3. FORM: 4-Pr-007-4-Fo-0003 Master plan
4. FORM: 4-Pr-007-4-Fo-0004 Meeting minutes
5. FORM: 4-Pr-007-4-Fo-0005 Customer requirement break down sheet
6. FORM: 4-Pr-007-4-Fo-0006 Technical report
7. FORM: 4-Pr-007-4-Fo-0009 Process qualification implementation
8. FORM: 4-Pr-007-4-Fo-0010 Periodical reliability test request
9. FORM: 4-Pr-007-4-Fo-0011 Master plan for periodical reliability test
10. FORM: 4-Pr-007-4-Fo-0012 4M review for product long tim re-run

Questionnaires:

Q1: Before trial run for sample, which design review must be hold?
- a. DR-1
- b. DR-2
- c. DR-3

Q2: Before shiping evaluation sample to customer, which design review must be hold?
- a. DR-1
- b. DR-2
- c. DR-3

Q3: After receiving customer evaluation on sample, which design review should be hold?
- a. DR-1
- b. DR-2
- c. DR-3

Q4: We should review "Customer requirement break down sheet" at:
- a. DR-0
- b. DR-1
- c. DR-2
- d. DR-3

Q5: Which stage we should discuss & setup the target about QCD for production line.
- a. DR-0
- b. DR-1
- c. DR-2
- d. DR-3

Q6: Draft OP, QC, FMEA, PS should be prepared before:
- a. DR-0
- b. DR-1
- c. DR-2
- d. DR-3

Q7: Quality document: OP, QC, FMEA, PS should be reviewed and update in which stage :
- a. DR-1
- b. DR-2
- c. DR-3
- d. DR-1, DR-2, DR-3

Q8: Who is consultor in DR meeting for process design qualification ?
- a. Group leader upwards
- b. Executive upwards
- c. Department manager upwards

Q9: In case the result of evaluation of New Product is failure, it should return back to which stage
- a. DR-0
- b. DR-1
- c. DR-2

Q10: In DR-1, which item should be reviewed?
- a. List out all requirement from customer spec and review one by one item
- b. Confirm finishing 4M preparation
- c. Issue Plan for trial run product
- d. a, b, c are correct

Questionnaires:

Q11: In which stage, quality document level 2 need to be issued as official version
- a. Trial Run
- b. DR-1 & DR-2
- c. DR-3
- d. Transfer to mass production initial control

Q12: Which stage we need to review the result of trial run compare with target setup.
- a. DR-0
- b. DR-1
- c. DR-2

Q13: The order of each action items in master plan for new product tranferring

a. Collect INPUT information ® DR-0 ® DR-1 ® DR-2 ® Trial run ® Evaluation of customer ® DR3 ® Transfer to mass production initial control

b. Collect INPUT information ® DR-0 ® DR-1 ® Trial run ® DR-2 ® Evaluation of customer ® DR3 ® Transfer to mass production initial control

c. Collect INPUT information ® DR-0 ® Trial run ® DR-1 ® DR-2 ® Evaluation of customer ® DR3 ® Transfer to mass production initial control

Q14: This procedure is applied for:
- a. Controlling of new product transfer
- b. Transfering manufacturing production line between diffirent factories in FJK group of company
- c. Both a and b

Q15: Which sections concern to Trial run stage?
- a. PRE, QAE, PRD, SES
- b. PRE, TRC, PRD, PTE
- c. PRE, QAE, TRC, PRD, SES, PTE, PLN

Q16: When we need to make internal periodical reliability test plan.
- a. Monthly
- b. Quarterly
- c. Yearly

Q17: Why do we need control long time re-run product
- a. Review new update of 4M and customer's requirement on the product
- b. Need to prepare 4M before re-run product conpletely
- c. Both a and b

Q18: When do you review Process qualification, MSA ?
- a. At DRO
- b. At DR1
- c. At DR2
- d. At DR3

Q19: When do you carry out Process qualification ?
- a. The results of the process cannot be fully verified by subsequent inspection and test.
- b. Receive customer' request for process qualification
- c. Both a and b

REVISION HISTORY

Date	PIC	Ver	Description content of change		Reason of change	Requester
			Old Content	New Content		
16-Sep-24	Phuoc10253	39	No section E	Add section E.Product testing flowchart (TSA) (page 5)	From Aug-2024, PDS is no longer available so process 8-pr-001 is obsolete and the product testing section for customers is retained, this part is merged into process 4-Pr-007.	QMR_Ms Bao Tram & MNF. Division manager_Mr Kien
26-Jul-24	Ban 10151	38	In page 2/13 A - Process design qualification SIC: PDS	In page 2/13 A - Process design qualification Cancel SIC: PDS	Re-organize section in FOV	MNF. Division manager_Mr Kien
16-Feb-24	Ban 10151	37	Title of procedure 4-Pr-007: PROCESS DESIGN QUALIFICATION & CHANGE CONTROL In page 3/15. B-Change control In page 6/15. Appendix A, B Questionnaires: including content for change control 	Title of procedure 4-Pr-007: PROCESS DESIGN QUALIFICATION Remove Remove Re-numbering after remove Change control related content Questionnaires: remove content for change control Appendix D: Identify special spec and simple/similar spec - Add new group: Fiber Laser, Sensor FBG	- Seperate "change control" in procedure 4-Pr-007 to new procedure 9-Pr-0014 Change control to apply for all changes in FOV system. Review & add for new production line	QMR_Ms Bao Tram & MNF. Division manager_Mr Kien
2-Jan-24	Ban 10151	36	In page 3/16: - Not yet define MSA - Form: 4-Pr-007-4-Fo-0004 Design review checklist for process design qualification. In page 3/16: - Step 2. Review and approval None In page 3/16 + Review PQ requirement in step DR-1 In page 7/16 Appendix D: PQ decision when apply new equipment or significant process' change In page 8/16 Appendix E: Define priority for periodical reliability test In page 9/16 Appendix F: 4M Review for product long time re-run In page 9/16 Appendix G: Identify special spec and simple/similar spec None.	In page 3/15: - Define which measuring process need to apply MSA, refer to Appendix G-MSA requirement - Form: 4-Pr-007-4-Fo-0004 meeting minutes. In page 3/15: Step 2. Review and approval + If the change is applied to process with PQ application, it's followed to appendix C) Process qualification requirement. + If the change is applied to process with MSA application, it's followed to appendix G) In page 3/15 + Review PQ requirement in step review and approval. In page 7/15 Delete appendix D. In page 8/15 Appendix D: Define priority for periodical reliability test In page 9/15 Appendix E: 4M Review for product long time re-run In page 9/15 Appendix F: Identify special spec and simple/similar spec Page 10/15 Appendix G: MSA requirement	- Establish MSA implementation. - Revised meeting minutes form for flexible use. - Make clear change for PQ application. - Added MSA application scope. - Correction. - Combine appendix D to appendix C.Process qualification requirement - Re-numbering appendix item. - Build MSA for measuring process	QMR_Ms Bao Tram & MNF. Division manager_Mr Kien
16-Sep-22	Ban 10151	35	Procedure name: PROCESS DESIGN QUALIFICATION & 4M AMENDMENT CONTROL V. Content B-4M amendment - Project leader control 4M amendment procedure - DR-1 at input for changes of machine/tool-jig + None	Procedure name: PROCESS DESIGN QUALIFICATION & CHANGE CONTROL V. Content B-Change control - PIC control change control procedure - DR-1 at input for changes of machine/tool-jig + Add Note: PIC attach the function & design concept to change control form and make clear designer's name & department in form "Design review checklist for change control"	- Standardize name and PIC for 4M change procedure. - Make clear this requirement for change control	MNF. Division manager_Mr Kien
11-Aug-22	Ban 10151	34	Title of procedure: "Standardized product transferring & 4M amendment II. Application 1. This procedure is applied to all type of products made in FOV. V.Content A. Normal product transferring - Demand of process design qualification to FOV step: Migration Plan: 4-Pr-007-4-Fo-0002 - DR1: Input: None Review in DR-1: Review detail requirement with content of draft version of QC flow chart and Operation procedure - Trial run Input: process specification, checksheet - DR2: Review in DR2 - DR3 Output: Department Manager upwards will make final decision to approve for new mass production. V.Content B. 4M amendment - Review and approval step: None - DR0: none - DR1 input: none Review in DR1: none Output: none -DR2 Review in DR2: Evaluate risk to setup Q-condition & set counter spec(if any), can use the FMEA form of Customer VI. Attached form 4-Pr-007-4-Fo-0001 4-Pr-007-4-F0-0003 4-Pr-007-4-Fo-0004 4-Pr-007-4-Fo-0005 4-Pr-007-4-Fo-0006 4-Pr-007-4-Fo-0007 4-Pr-007-4-Fo-0011 4-Pr-007-4-Fo-0012 4-Pr-007-4-Fo-0015 4-Pr-007-4-Fo-0016 Questionnaires	Title of procedure: "Process design qualification & 4M amendment control" II. Application 1. This procedure is applied to all type of products have been qualified by customer or FOV design section follow to: 8-Pr-0001. V.Content A - Process design qualification - Demand of process design qualification to FOV step: Obsolete "Migration Plan: 4-Pr-007-4-Fo-0002" - DR1: Input: Added WI or FMEA from customer if any Review in DR-1: Review detail requirement with content of draft version of QC flow chart, Operation procedure, FMEA and PS - Trial run Input: Quality document: OP, QC, FMEA, PS, check sheet, template. - DR2: Review in DR2: Review draft QC flow chart, Operation procedure, FMEA, PS with customer requirement and actual trial run - DR3 Output: Section manager upwards will make final decision to approve for new mass production. V.Content B. 4M amendment - Review and approval step: added "Note: all DR meeting must be joined and consulted by at least one executive position upward. Project leader should follow the guideline from DR checklist to ensure that all items in DR must be reviewed". - DR0: added "'- Consider the impact to cost (ROI if change concern to new investment for machine/ tool) and delivery for the change " - DR1 input: added "DFMEA of tool if any" Review in DR1:added "Review risk effect of this change to horizontial site" Output: add " Make clear risk effect of this change to horizontal site" -DR2 Review in DR2: Re-evaluate risk and update P-FMEA for this change. VI. Attached form 4-Pr-007-4-Fo-0001 4-Pr-007-4-F0-0002 4-Pr-007-4-Fo-0003 4-Pr-007-4-Fo-0004 4-Pr-007-4-Fo-0005 4-Pr-007-4-Fo-0006 4-Pr-007-4-Fo-0007 4-Pr-007-4-Fo-0008 4-Pr-007-4-Fo-0009 4-Pr-007-4-Fo-0010 4-Pr-007-4-Fo-0011 4-Pr-007-4-Fo-0012 Questionnaires: update content for almost questionnaires	Review and standardize document to improve design review Issue new form and re-arrange form No. for better document control Update base on change of the procedure	QMR_Ms Bao Tram & MNF. Division manager_Mr Kien

1-Jun-22	Trung 10089	33	1) Separate workflow: A - Normal product transferring and 4M Amendment	1) Separate workflow: A - Normal product transferring B - 4M Amendment	Make appropriate requirement and control to each application	QMR_Ms Bao Tram & MNF. Division manager_Mr Kien
			A - Normal product transferring and 4M Amendment DR1 (Input):	B - 4M Amendment: DR1 (Input): - Add: For changes of machine/tool-jig, review and confirm the function and design concept of machine/tool	Make clear instruction for input information when PRE review to improve machine/tool-jig	
			2) APPENDIX A: Exception application list for 4M amendment request	2) APPENDIX A: Exception application list for 4M amendment request - Remove: Breakdown control of changes - Simplify requirement for: Human & Document	Internal review (avoid duplicated with relating procedures)	
			3) APPENDIX B: Significant 4M Amendment and approval route 1. Relate to Customer in list of "special customer" 2. Requirement in customer specification 3. Requirement by E-mail or other instruction from customer 4. General requirement (IEC, JIS, etc.) from market 5. Corrective action promised to customer 6. Products Material change (not consumption) or process flow change controlled QC flow. 7. Possibility of quality change or risk of quality level down after shipping. 8. Possibility that Customer can't use by current method 9. Internal requirement/ specification in level 2 document 10. Internal corrective action of FOV 11. Consumption material in process 12. Layout of workshop 13. Production base (Factory) change	3) APPENDIX B: Significant 4M Amendment and approval route 1. Criteria/ specification or method that agreed with Customer 2. Criteria/ specification or method that required by Customer or relating Standard 3. Risk of quality or operating that impacted to final customer (user) directly	Internal review to make the description in general that easier for user.	
				Remove 9 ~ 12	Re-consider approval level of change (assign to section manager level)	
			4) Appendix F: 4M Review for product long time re-run	4) Appendix F: 4M Review for product long time re-run - Remove pictures of program user interface	No need for general procedure	
			VI. Attached form: 4-Pr-007-4-Fo-001 4-PR-007-4-FO-002 4-Pr-007-4-Fo-003 4-Pr-007-4-Fo-004 4-Pr-007-4-Fo-005 4-Pr-007-4-Fo-011 4-Pr-007-4-Fo-012	VI. Attached form 4-Pr-007-4-Fo-0007 4-Pr-007-4-F0-0006 4-Pr-007-4-Fo-0003 4-Pr-007-4-Fo-0004 4-Pr-007-4-Fo-0005 4-Pr-007-4-Fo-0011 4-Pr-007-4-Fo-0012	Standardize number with 4 digits as 0-PR-001	
			Questionnaires:	Questionnaires: update content for Q.1 & Q.2	Internal review as revision for APPENDIX A	
			Questionnaires:	Questionnaires: update content for Q.12	Update for new instruction in part B - 4M Amendment: DR1 (Input)	