Quality Management System for Supplier(MM06)

Acknowledgment

It is Fabrinet's goal to provide our customers with: (i) products that manufactured with the greatest degree of care; (ii) products are delivered on time; (iii) real-time communications and (iv) manageable costs.

These goals can be achieved with the strong support and commitment from our suppliers. We are confident that your company will share in and embrace Fabrinet's goals. This document is not intended to alter or change any pre-existing or required supplier terms and conditions as set forth by Fabrinet. Suppliers shall read and understand the requirements/guidelines set forth and communicate any concerns to Fabrinet directly.

Acknowledgment Category of parts/service:

1. General Requirements *(item 1-8)*
2. Automotive Requirements *(item 9)*
3. Medical Requirements *(item 10)*

1. Purpose

This document specifies requirements for Supplier's Quality Management System which products or procures part and/or services that will be provided to Fabrinet (hereinafter referred to as "FBN").

2. Application

2.1 This document shall apply when incorporated by reference in a Purchase Order or Contract between FBN and Supplier which supplies manufactured or purchased products and/or Service

2.2 Where any requirements of this document cannot be applied due to the nature of Supplier and its product, it can be considered for exclusion. Exclusions are made when requirements in this document affect the Supplier's ability or responsibility to provide a product that meets customer and application regulatory requirements. It is the responsibility of the supplier to communicate any exclusions to FBN Supply Chain.

2.3 Relationship with other requirements, Supplier shall comply with all contract requirements and have a responsibility to supply the products which conform to the requirements. When there is conflict discovery between this document and the contract requirement, the contract requirement shall take precedence.

2.3 Only the latest released revision of MM06 is effective. The supplier shall follow the revised requirements as long as the cost is not affected. It is the supplier's responsibility to communicate any effect to the cost caused by a revision to MM06 to FBN Supply Chain.

3. Definition

3.1 Supplier:

The domestic or overseas organization who provide parts/assemblies/processes, tooling, test/service, raw material, software, hardware and equipment.

3.2 Outside Manufacturing Services:

Manufacturing and support service products in accordance with Fabrinet that are provided drawing and production planning document. Outside manufacturing/division includes parts which are manufactured per work order or services provided.

3.3 Supplementary Quality Assurance Requirements:

Additional requirements which is specified on contract/purchase order and are provided to the supplier separately from this document.

3.4 Supplier Quality Assurance Requirements:

Quality assurance requirements provided to supplier that are specific to FBN.

4. General Requirements

4.1 Certificate of Quality Management System:

Supplier shall establish and maintain an effective Quality Management System that complies with this document's requirements in order to provide their products and services to Fabrinet and be approved by Fabrinet

4.2 Additional Supplier Quality Assurance Requirements:

In addition to the provisions provided in this document, including Additional Quality Assurance Requirements, the supplier shall also comply with the following quality assurance requirements:

a) Quality Assurance/Inspection and test requirements noted on applicable design specifications (namely Drawing, Special process, and Material specifications).
b) Quality assurance requirements noted on the contract/purchase document
c) Quality assurance requirements under the regulations
d) Supplier quality assurance requirements which are distributed with the contract/purchase document.

4.3 Supplier Performance Review:

Fabrinet shall perform Supplier Quarterly Business Review (QBR) for identified key suppliers on Quality, Responsiveness, Delivery, and Cost. Regarding the portion with low score, Supplier shall improve the score in compliance with Fabrinet's requirements.

4.4 Periodic Audit:

Unless otherwise specified, Fabrinet approved suppliers shall acknowledge that Fabrinet reserves the right to audit or monitor the quality management system of identified key suppliers no less than once a year during the life of the contract.

4.5 Corrective Action:

When Fabrinet issues a written corrective action request, Supplier shall provide a response to the corrective action request with full 8D report format within the due date as identified by Fabrinet.

4.6 Right of Entry:

Fabrinet and/or Fabrinet's customer and regulatory authorities shall be afforded the right to verify conformity of the supplier's quality management system or verify the product in accordance with the specified requirements at the supplier's facilities and/or the supplier's subcontractor facilities.

a) Upon request, the quality records, equipment, and/or personnel shall be made available to Fabrinet and/or Fabrinet's customer for operation of equipment and other support as deemed necessary.
b) FBN reserves the right to verify the conformity of the supplier's quality management system at the supplier site upon request.

4.7 Cancellation of Quality Management System Approval:

When the supplier comes under the following conditions, FBN has the right to cancel the approval of the Quality Management system for the Supplier without any notice:

a) In the case of a major non-conformance is found in the product and/or service and the supplier is not able to comply with the specifications under FBN's discretion.
b) If the business with Fabrinet has ceased for two years.
c) If FBN requests to visit and enter the facility of the supplier and it is refused without proper justification as viewed by FBN.
d) If FBN requested corrective action is refused or has not been performed adequately without an acceptable justification.

4.8 Responsibilities of Supplier:

4.8.1 When it comes under the following conditions, the supplier shall notify FBN with a written letter within 7 days.

a) When it is discovered that a discrepant product has already been delivered and/or has been shipped in suspected.

b) Notification shall include a clear description of the discrepancy, Part numbers (Serial, Lot, and Manufacturing date), Part description, Part revision, quantity, delivery date, corrective action, and others.

c) Non-conforming control, deviation from drawing/specification is needs FBN to approve prior to make shipment.

d) Cancellation or Suspension any issued quality management certificate by a 3rd party registrar (ex. ISO Certification)

4.8.2 In case of doubt as to the applicability of this specification or its interpretation, the supplier is responsible to inform Fabrinet prior to implementation of any action which may affect hardware or its documentation.

4.8.3 Return Material Request, supplier shall promptly respond to RMA / OSP / Credit note request per SQE and/or Buyer request.

4.8.4 Supplier shall define the necessary avoidance, detection, mitigation, and disposition processes to prevent counterfeit parts supply to Fabrinet. Supplier shall develop and implement a fraudulent/counterfeit EEE parts control plan that documents its processes used for risk mitigation, disposition, and reporting of suspect or confirmed Fraudulent/counterfeit EEE parts. Supplier is responsible for ensuring that all supplied parts/materials to Fabrinet comply with requirements and are authentic

4.8.5 The supplier must ensuring that their personnel are aware of:

a) Their contribution to product or service conformity
b) Their contribution to product safety
c) The importance of ethical behavior

4.9 Quality Assurance Requirements:

4.9.1 Quality Target

At Fabrinet Incoming Inspection	At Fabrinet Production line
Target/Commitment of Lot Acceptance Rate (LAR)	Target /Commitment of DPPM
100% LAR	≤35 DPPM

4.9.2 Management of Production Process

a) Process Capability Index Cpk, Goal >= 1.33

b) The minimum acceptable level for quality for critical parameters per Drawing identified and record on Quality Assurance report.

c) Statistic Process Control (SPC)

1) The SPC should be applied for process monitoring on critical parameters per Drawing identified and record on Quality Assurance report.

d) If Supplier falls below the limit, the plan and actual improvement status should be reviewed by the management of Supplier. Supplier must provide this information promptly if Fabrinet requires.

1) GR&R (Gauge Repeatability & Reproducibility) test result

2) Supplier shall implement GR&R as the tool to ensure the assurance for quality.

3) GR&R should be implement to the measuring equipment that measure parameters concerning to quality.

4) Supplier and FBN's Supplier Quality Engineering department shall adjust and determine the object equipment.

5) Supplier shall submit the data upon Fabrinet request.

6) The criteria appointed by Fabrinet are as follows.

7) Supplier shall observe the criteria, and implement the improvement, if it is necessary.

Gage Study Decision Rules	**% Contribution**	**% Tolerance, %Study Var, %Process**	**Number of Distinct Categories (NDC)**
Acceptable	1% or less	Under 10%	5 or more data category
Potential Acceptable	1% - 9%	10% - 30%	2-4 data category
Not Acceptable	9% or greater	Over 30%	1 data category

e) FMEA (Failure Mode and Effect Analysis)/ DFM (Design For Manufacturing)

Supplier shall execute FMEA/DFM to prevent the occurrence of non-conforming parts and failure, as the tool to stabilize the quality and the process. Then the result of analysis should be referred to Supplier In-process inspection data and Out-going inspection data monitoring.

f) CI (Continuous Improvement)

Supplier shall make the CI for the enhancement of quality assurance, the decrease of failures/DPPM, and the meet Very good level of Performance rating (Quarterly Business Review-QBR)/ Assessment rating (On-site audit), then progress the plan and actual improvement status should be reviewed by the management of Supplier. Supplier must provide this information promptly if Fabrinet requires.

Consider level of performance rating/ Assessment rating for step of Continuous improvement:

Performance rating level (QBR)

0-69	Unacceptable
70-74	Conditional Acceptable
75-79	Acceptable
80-89	Very good
90-100	Excellent

Note: If some criteria in each element were a weighted score of 0-1, that score downgraded the performance of that element to be Unacceptable level and required corrective action under the SCAR report.

Assessment rating level (On-site audit)

0-69	Unacceptable
70-79	Conditional Acceptable
80-89	Acceptable
90-95	Very good
95-100	Excellent

Note: A downgrading rating level is applied when a critical NC has been found in an on-site audit, The overall assessment rating level criteria were reviewed from "Excellent"," Good" and "Acceptable" levels to "Conditional accept" level.

g) Failure Analysis

Supplier shall perform Failure Analysis/Investigation if required by Fabrinet. Supplier must report preliminary report within 24 hours after received failed product. Supplier should be expedited in regard to complete of Failure Analysis/ Investigation report submission to Fabrinet as fast as possible/reasonable time line.

4.10 Sub-supplier Management:

Supplier shall have the occupation of Supplier Quality Engineering (SQE)/ Quality Assurance (QA) and needs to be responsible for quality management of sub-supplier.

4.11 Change Notification:

Supplier shall submit the changed proposal by sending mail to user name pcn@fabrinet.co.th for any changes in regards to the following:

1. Form, fit, function of the product
2. Reliability of the product
3. Changes to the manufacturing process, materials, machines, and manufacturing location
4. Changes to staff in charge of Quality and Specification & Environmental performance,
5. Changes to sub-supplier(s) involving the product
6. Any changes that can possibly affect quality and performance characteristics

Supplier shall submit the changed proposal by sending mail to user name pcn@fabrinet.co.th This group mail is includes SCE names of each commodity at FBN. The official approval by Fabrinet is required prior to change implementation.

The Processes Change Notification (PCN) should notify to Fabrinet as soon as possible. Our preference is at minimum 6 months in advance as Fabrinet need to get the approval of Change from Customer before implementation. If any delay or lacking of PCN causing quality impact and/or Fabrinet's customer complain. The penalty will be applied according to cost and business impact.

4.12 Traceability:

Supplier must keep the required production history in order to assure the traceability and to specify the object range of problem, if the occurrence of defective product quality and failure. Supplier must supply this information promptly if Fabrinet ask for the production history Following are the minimum requirements and Supplier must keep this information for at least 3 years.

-Production Date

-Production Line

-Production Equipment

-Revision

-Cavity No.

-Batch or Lot number

-Others

4.13 Storage, Handling, Packing and Transportation:

4.13.1 The supplier shall ensure proper environmental conditions at the storage sites for part, semi-finished and finished products.

4.13.2 The supplier shall use a first-in, first-out system when taking parts out of a warehouse.

4.13.3 The supplier shall establish a packing method that ensures the safety of the product during transportation and obtain approval for it from Fabrinet's PPAP or FAI approval.

4.13.4 The aging control/Lifetime control as of received at Fabrinet shall be managed and clearly identified on the Shipping label and the shelf life shall be valid at least 6 months (exceptions include thermal pad and adhesive tape, epoxy which are 2 months).

4.13.5 The label information for Electrical, PCB, Flex Circuit, PCBA, Adhesive, and Chemical parts commodity shall consist of the below list,

Required:

FBN Part Number

Part Description

Part Revision

Supplier Name

Manufacturer (MFG) Part Number

Lot Code/Production Lot

Manufacturer (MFG) Date

Manufacturer (MFG) Name

Expire Date

Quantity

If applicable:

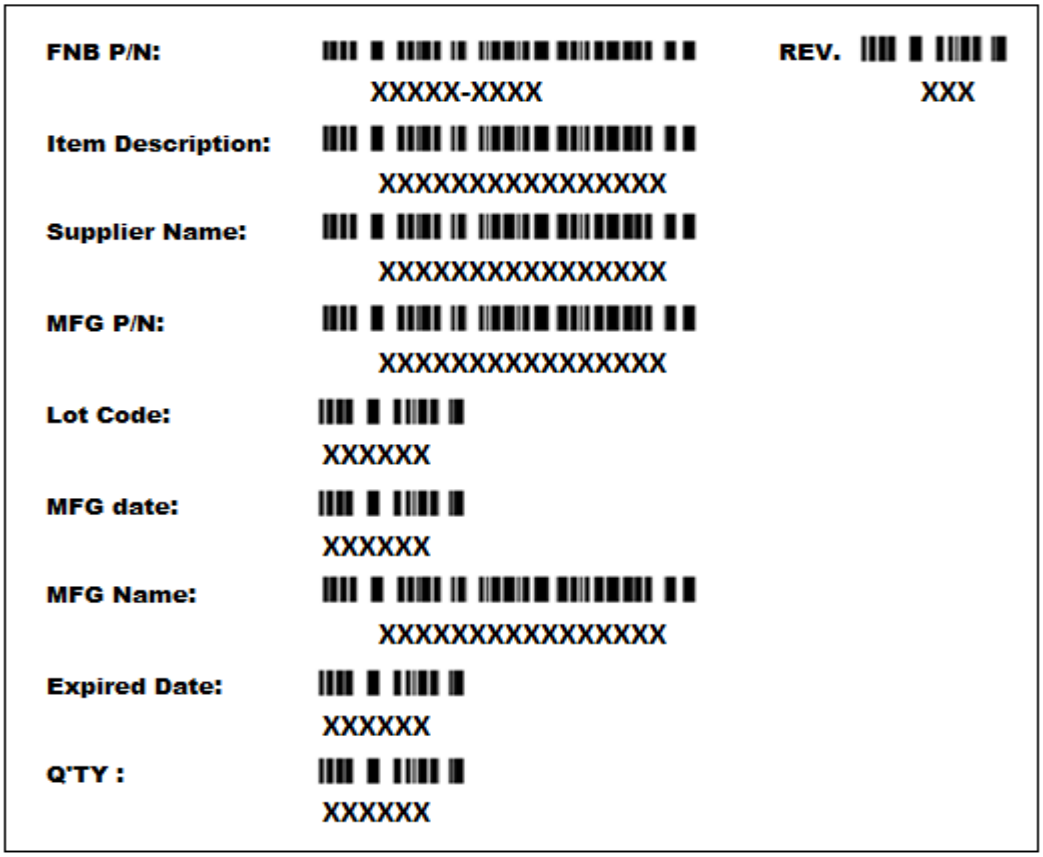
Total boxes/ Packs

Box Count (Box # of Total Boxes)

Country of Origin (Example Made in China)

PO number and Invoice/shipment number.

Example of Label information (per item 4.13.5)



4.13.6 The label information for Optical, Mechanical, Hardware, Sub-Direct, and Other parts commodity shall consist of the below list,

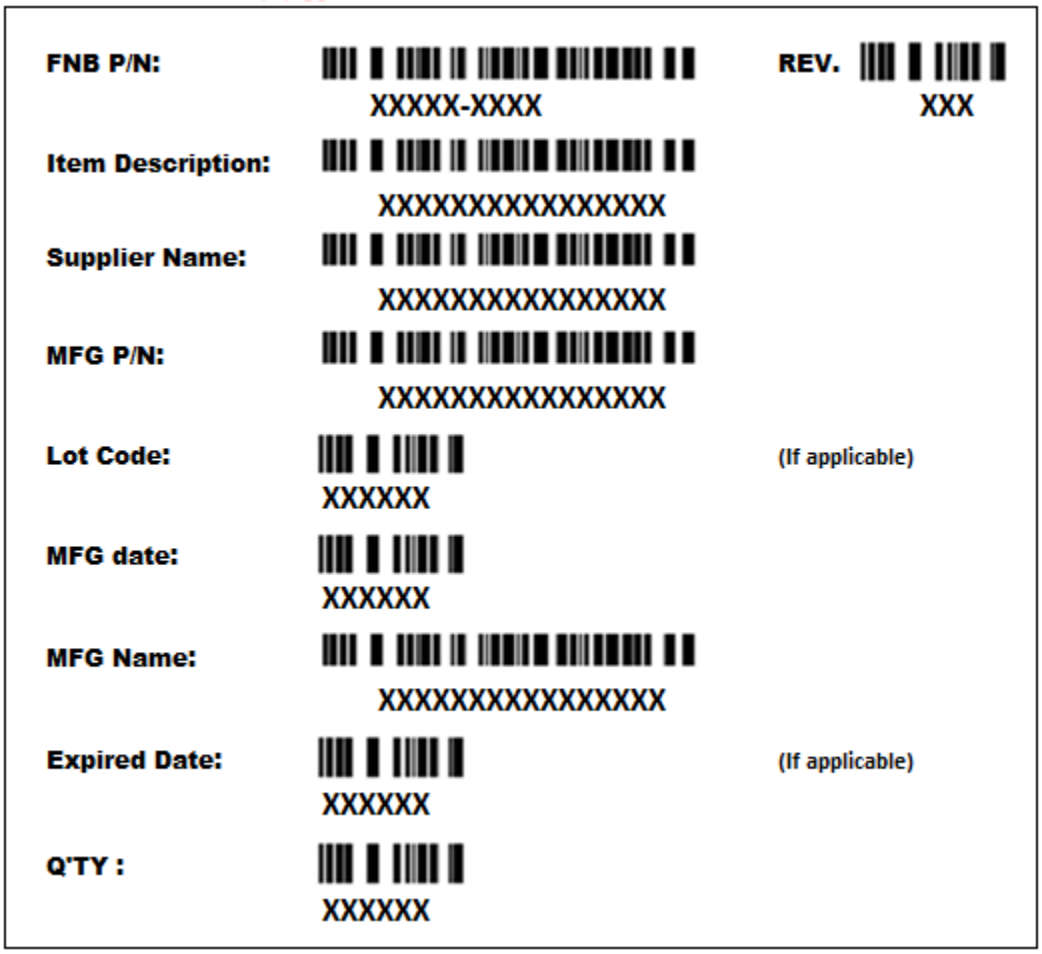
Required:

- FBN Part Number
- Part Description
- Part Revision
- Supplier Name
- Manufacturer (MFG) Part Number
- Manufacturer (MFG) Date
- Manufacturer (MFG) Name
- Quantity

If applicable:

- Lot Code/Production Lot
- Expire Date
- Total boxes/ Packs
- Box Count (Box # of Total Boxes)
- Country of Origin (Example Made in China)
- PO number and Invoice/shipment number.

Example of Label information (per item 4.13.5)



4.14 Material Environment Compliance: [MEC)

a) Supplier shall execute the control for Material Environment Compliance as appointed by Fabrinet's Customers; namely Restriction of Hazardous Substances (RoHS), Material Declaration (REACH, JAMP, IPC-1752-X, RBA, GeSI, CMRT, etc), C of C for quality per print, Authentic C of C, and others.

b) As a FBN supplier we expect that your products, components or substances supplied to Fabrinet will meet the requirements of country, federal, state and local environmental regulations. The list below includes some of the regulations; however, compliance is not limited to these. Additional information may be required such as certification to any of

the following or chemical composition of products, components and/or substances. If you suspect that Products, components or substances supplied to FBN are not compliant, please contact the appropriate buyer or supply chain representative immediately.

- REACH (Registration Evaluation Authorization and Restriction of Chemicals) Regulation 1907/2006/EC
- WEEE (Waste Electrical and Electronic Equipment) Directive 2001/96/EC
- RoHS (Restriction of Hazardous Substances) EU 2011/65/EU and China
- Packaging Directives 94/62/EC, 2004/12/EC, COM Decision 97/129/EC
- Battery and Accumulator Directive 2006/66/EC
- California Proposition 65
- Etc.

In case that FBN requires, supplier shall submit the data of contained substance base on the item requirement of Fabrinet's customers within appropriate time line.

4.15 The Responsible Business Alliance (RBA):

The Responsible Business Alliance (RBA), formerly know EICC, code of conduct establishes standards to ensure that working conditions in the electronics industry supply chain are safe. Suppliers shall conform with RBA standards, refer to https://www.responsiblebusiness.org/code-of-coduct/

4.16 Corporate Social Responsibility (CSR):

FBN strongly prefers that suppliers shall be responsible to provide sufficient resource to implement and maintain a Corporate Social Responsibility program and contribute to the well-being of communities and society through environmental and social measures.

4.17 Environmental Management System (ISO 14001 or GHG):

FBN strongly prefers that suppliers execute or plan to comply with Environmental Management System such as ISO 14001, GHG Emission Reduction program and Energy Efficiency management as part of the management system used to manage environmental aspects, fulfill compliance obligations, and address risks and opportunities. Note that this may become a requirement in the future.

4.18 Cyber Security Management System (ISO 27001):

FBN strongly prefers that suppliers execute or plan to comply with Cyber Security Management Systems such as ISO 27001. Note that this may become a requirement in the future.

4.19 Occupational Health And Safety Management Systems (ISO 45001):

FBN strongly prefers that suppliers execute or plan to comply with occupational health and safety management systems as ISO 45001 provides a framework for organizations to manage risks and improve OH&S performance. Note that this may become a requirement in the future.

5. Quality Assurance Management Requirements

a) ISO 9001 Inspection and Test Quality System requirement
b) If the supplier provides a calibration or a test service, shall be approved by the certification body which is approved by the applicable country accreditation.

6. Quality Records Retention Requirement

a) Unless longer periods are specified by the purchase document or communication by Fabrinet,

the supplier shall maintain a Quality record of file and be available to Fabrinet for a minimum 3 years

and/or 5 years following the end of the calendar year in which the contract is completed.

b) Upon request, the quality record shall be provided to Fabrinet within fifteen days

c) The supplier shall notify Fabrinet for authorization before destroying any of these records within the record retention period.

7. Offer of Quality Monitor in process

7.1 Reporting Item and Frequency

Supplier shall execute quality monitoring which such enables to grasp the production quality and production process control condition. And regarding the data of the items which are determined with SQE section/Materials Department, supplier shall periodically report them to Fabrinet. The item which is required to report should be selected from Out-going inspection, In-process and Reliability Testing. The items of report

7.2 Reporting Format

Supplier shall supply these quality monitor data to Fabrinet in supplier's design form.

8. Distributor, Agent

8.1 The requirement apply to distributors that are buying product strictly from other suppliers and sealing them to Fabrinet without adding value to the product other than repackaging

8.2 Quality System Requirements

a. Distributor's purchasing documents shall contain data clearly describing the product ordered including the type, Class, Grade, or other precise identification,
b. The title of other positive identification, and application issues of specifications, drawings, process requirements, other relevant technical data.
c. Distributor shall review and approve purchase documents for adequacy of the specified requirements prior to release.
d. Modification of supplier by distributor is strictly prohibited except where approved by the original manufacture of Fabrinet.
e. Distributor shall ensure the original manufacture's name and lot or batch number as applicable, are references on the supplier's packing sheet that accompanies each shipment.
f. Distributor shall maintain communication channel with the original manufacturer for transfer of any Fabrinet questions regarding the product.
g. Distributor shall verify purchased product at the subcontractor's premises or supplier's premises.
h. The distributor shall apply appropriate methods for preservation and segregation of product when the product is under the distributor's control. The condition of products in stock shall be assessed at appropriate intervals in order to defect deterioration, or other nonconforming conditions.
i. Prior to delivery, distributor shall verify that product and accompanying documents meet Fabrinet requirements.

9. Quality Management System for Automotive Suppliers

(Note: a portion# in Quality Management System for Automotive Suppliers follow as IATF 16949 number format. The following section applies to suppliers that provide material for automotive end customers)

A.1 Scope

Refer IATF 16949, no additional requirements.

A.2 Normative references

Refer IATF 16949, no additional requirements.

A.3 Terms and definitions

Refer IATF 16949, no additional requirements.

A.4 Context of the organization

Refer IATF 16949, no additional requirements.

Suppliers shall ensure that process, products and services conform to requirements.

Suppliers shall include all products and services that affect customer requirement such as sub-assembly, sequencing, sorting, rework and calibration services in the scope of their definition of externally provided products, processes and services.

A.5 Leadership

Refer IATF 16949, no additional requirements.

A.6 Planning

Refer IATF 16949, no additional requirements.

A.6.2.2.1. Quality Objective and Planning to achieve them:

Fabrinet and Automotive customers expect Zero-Defect during the product life cycle.

Thus, it is our expectation that suppliers provide Fabrinet with Zero-Defect mindset and culture.

A.7 Support

Refer IATF 16949, with the additional requirements as below:

A.7.5.3.2.1 Record retention

Suppliers are required to establish document information and implement an effective Quality Management System.

Table A1: Retention Record Detail

Record Description	Retention Period
Quality Performance Record (e.g. control charts, inspection and test result)	Product Active Life + 1 year
Purchase Orders and Amendments	Product Active Life + 1 year
Purchase Orders for Customer Owned Tooling	Product Active Life + 1 year
First Article Inspection Record	Product Active Life + 1 year
Production Part Approval Record (PPAP)	Product Active Life + 1 year
Tooling Preventive Maintenance records	Product Active Life + 1 year
Engineering Changes	Product Active Life + 1 year

Note: The length of time that the product is active for production and service requirement refer IATF16949 item 7.5.3.2.1 Record retention.

A.8 Operation

Refer IATF 16949, with the additional requirements are as below:

A.8.2.3.1.3 Customer-designed special characteristics

The supplier shall flow down customer-designed special characteristics throughout the process steps and control documents including drawings, FMEAs, Control Plans and work instructions

A.8.4.1.2 Supplier Selection Process (Fabrinet's sources)

Fabrinet's supplier selection process shall include:

- an assessment of the selected supplier's risk to product conformity and uninterrupted supply to Fabrinet
- relevant quality and delivery performance
- an evaluation of the supplier's quality management systems

Other supplier selection criteria that should be considered include the following:

- volume of automotive business
- financial stability
- purchased product, material, or service complexity
- required technology (product or process)
- adequacy of available resources
- design and development capabilities
- manufacturing capabilities at least Cpk 1.33 for special characteristics, Unless the customer specifies otherwise in the supplier manual, drawing, etc.
- business continuity planning
- logistic process
- customer service

A.8.4.1.3 Customer-directed sources (also known as "Directed-Buy)

When specified by Fabrinet's customer, Fabrinet shall purchase products, materials, or services from customer-directed sources.

All requirements of this Session (except the requirement A.8.4.1.2) are applicable unless specific agreements are otherwise defined by the contract between Fabrinet and suppliers

A.8.4.2 Type and extent of control – supplemental

Suppliers shall have a documented process to identify outsourced processes and to select the types and extent of control used to verify conformity of externally provided products, processes and services as customer requirements.

A.8.4.2.2 Statutory and Regulatory Requirements

Suppliers shall document their process to ensure that purchased product, processes and services conform to current applicable statutory and regulatory requirements in the country of receipt, the country of shipment and the customer-identified country of destination, if provided.

If the customer defines special controls for certain products with statutory and regulatory requirements, supplier shall ensure for implemented and maintained as defined.

- Guidance on statutory and regulatory requirements is given in End of Life Vehicle - International Material Data System Directive (ELVD) 2000/53/EU

- Regulation EC 1907/2006 on Registration, Evaluation, Authorization (and Restriction) of Chemicals (REACH)
- 17 CFR Parts 229 and 249 Conflict Minerals Reporting - that materials or production process for those components purchased by Automotive customers or Automotive customers third party suppliers meet the conflict mineral reporting per the requirements set forth in section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010
- the Supplier shall enter all component Material and Substance Data using the International Material Data System (IMDS).

A.8.4.2.4 Supplier Monitoring

At a minimum, the following supplier performance indicators shall be monitored by Fabrinet :

- Delivered product conformity to requirement such as %IQA LAR, Fabrinet Internal PPM and SCAR related to material issues, number of customer incidents.
- Fabrinet's customer disruptions at the receiving plant, including yard holds and stop ships
- Number of customer field return and recalls.
- On-time delivery schedule performance such as OTD%.

If provided by the Fabrinet's customer, the following shall also be included in the performance monitoring

- special status customer notification related to quality or delivery issues
- dealer returns, warranty, field actions, and recalls

A.8.4.2.4.1 Second-party audits by Fabrinet at Supplier sites

Supplier shall acknowledge that Fabrinet reserves the right to perform the audit by periodically to manage suppliers for the following:

- to develop supplier for QMS achieve the TS/IATF 16949
- to improve the supplier performance link with the QBR program
- review supplier risk assessment
- to conduct Product audits
- to conduct Process audit

Based on a risk analysis, including product safety/regulatory requirements, performance of the supplier, and QMS certification level.

A.8.4.2.5 Supplier development

Suppliers of automotive products and services shall develop, implement and improve a quality management system certified to ISO 9001, unless otherwise authorized by the customer, with the ultimate object of becoming certified to this Automotive QMS Standard. Unless otherwise specified by the customer, the following sequence should be applied to achieve this requirement:

- Certification to ISO 9001 with compliance to TS/IATF 16969 through 2nd party audit done by Fabrinet's SQA team

- Certification to TS/IATF 16949 through third party audits.

Supplier to an organization is so small as to not have adequate resources to develop a system according to IATF16949:2016 or ISO 9001:2015, certain specified elements may be waived by the organization of their supplier. The organization shall have decision criteria for determining "specially designated small suppliers". Such decision criteria shall be in writing and applied consistently in the application of this provision. The existence and use of such decision criteria shall be verified by 3rd party auditors.

NOTE 1: "Small" may also refer to volume supplied to automotive.

A.8.4.3 Information for supplier

Fabrinet shall communicate to suppliers the requirements for:

- the processes, products and services to be provided
- the approval of product & services, methods, processes & equipment and the release of products and services
- competence, including any required qualification of persons
- the supplier interactions with the organization
- control and monitoring of suppliers' performance to be applied by Fabrinet
- verification or validation activities that Fabrinet or our customer, intends to perform at the suppliers' premises

The supplier shall pass down all applicable statutory and regulatory requirements and special product and process characteristic to their sub-suppliers and require to cascade all applicable requirements down the supply chain to the point of manufacture

A.8.6.2 Layout inspection and functional testing

The Supplier shall perform annual dimensional and functional testing for each component and submit result to assigned Fabrinet /or Fabrinet's Customer upon request. Layout inspection is the complete measurement of all product dimensions shown on the design drawing.

A.8.6.6 Acceptance Criteria

For attribute data sampling plan such as Incoming inspection or Out-going inspection, the acceptance level shall be zero defect (C=0)

A.9 Performance evaluation

Refer IATF 16949, no additional requirements.

A.10 Improvement

Refer IATF 16949, with the additional requirements as below:

The Supplier's management will ensure that the Quality Requirements, including without limitation, in this manual, are thoroughly distributed, understood, and maintained, and that adequate levels of authority have been established to ensure the continuous improvement of the Quality System.

A.10.2.6 Customer complaints and filed failure test analysis

Supplier shall perform analysis on customer complaints and field failures return, including any returned parts and shall provide problem solving and corrective action to prevent recurrence by using 8D report methodology with the due date as following.

- The containment actions need to provide within 24 hours once receive the notification
- Interim failure analysis report shall be submitted within 24 hours once receive the claimed part
- Root cause analysis and corrective action plan due date is defined by Fabrinet SQE

10. Quality Management System for Medical Device Suppliers

Suppliers are required to establish, document, and implement an effective Quality Management System. The Supplier's management will ensure that the Quality Requirements, including without limitation, in this manual, are thoroughly distributed, understood, and maintained, and that adequate levels of authority have been established to ensure the continuous improvement of the Quality System.

For medical device suppliers shall be certified ISO9001 and it is preferred ISO 13485 certified. For Suppliers that are not certified to the specified ISO standard, it is preferred that those Suppliers have a plan in place to become certified and can demonstrate progress toward that plan.

In addition to the requirements contained in this Manual, the Fabrinet Sourcing Organization will determine if a Quality Agreement is needed between Fabrinet and the Supplier. Once the need is determined, it is our expectation that the Supplier will work with Fabrinet to put this agreement in place.

Quality Agreements outline the Supplier specific quality requirements and Quality Requirements may be in the form of a Quality Agreement, PO, and/or this Manual. The Supplier must also provide immediate notification to Fabrinet if it receives a warning letter from the FDA.

10-1). Design History File

Suppliers are responsible for maintaining a Design History File (DHF) for the Product. This will contain or reference the records necessary to demonstrate that the design was developed in accordance with the design plan, per the applicable Quality System Requirements. Supplier shall retain records of the Product DHF for the agreed upon time, as stated in the Quality Management Agreement. Incase Fabrinet require information, Supplier shall provide the DHF within appropriate time line. Suppliers shall document results of the design reviews, design verification and the design validation.

10-2). Control of records

Records must be stored in an environment that will prevent deterioration, damage, or loss, and must be readily accessible to Fabrinet upon request.

Supplier will make available any and all quality Records, within two (2) working days, upon request by Fabrinet or any regulatory body such as the FDA.

Electronic record approvals and storage should comply with 21 CFR Part 11 requirements.

10-3). Record Retention

All quality Records shall be retained for a period of time equivalent to the design and expected life of the device, or as otherwise required by a Quality Agreement but in no case less than three (3) years from the date of shipment.