ThermoFisher SCIENTIFIC

Supplier Quality Manual

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About Thermo Fisher Scientific

INTEGRITY

- Honor commitments
- Treat others with dignity and respect
- Communicate openly and encourage candid feedback
- Be accountable for successes and failures
- Be a role model for our values

INTENSITY

- Drive to "win/win"
- Focus on the desired result
- Work with speed, passion and a can-do attitude
- Win with dignity, lose with renewed commitment
- Hold ourselves to a higher standard

INNOVATION

- Demonstrate a passion for discovery and learning
- Raise the bar, push the standard
- Recognize opportunities and take risks
- Practice continuous improvement
- Learn from the best practices

INVOLVEMENT

- Team up with our Strategic Suppliers to win together
- Listen actively; communicate completely
- Be a role model in everything you do
- Think and act globally
- Seek out challenges

THERMO FISHER SCIENTIFIC – QUALITY POLICY

Thermo Fisher Scientific will provide cost effective and reliable products and services at a level of quality that meets or exceeds our customer's expectations. Our goal-driven employees strive for continuous improvement in quality, service, cost containment, technology, and safety.

1 INTRODUCTION

Thermo Fisher Scientific is the world leader in serving science. Our products enable the global scientific community to perform their jobs more effectively. We depend on the performance of our Suppliers to provide us with the materials and services necessary to meet the needs of our customers. We firmly believe that continually improving our products and processes is a key to continued growth, profitability and success.

The foundation of a good relationship with our Suppliers is open, collaborative, and proactive communication. Only by clearly stating our requirements and expectations of our Suppliers can we hope to mutually benefit and build upon our relationship.

Our Suppliers are responsible for ensuring that the materials, products and services they provide to Thermo Fisher Scientific are of the highest quality and they meet all documented requirements and specifications, that they're delivered as scheduled, and that any service related issues are dealt with promptly.

2 PURPOSE OF THIS MANUAL

The purpose of this manual is to provide a standard to all Suppliers for Quality System Management and Performance. Suppliers of production related materials and services are subject to the requirements of this standard. The manual is not intended to replace the language contained in any individual agreements, contracts or specifications, but is intended to be an explanation of the minimum quality requirements upon which other requirements and expectations are built. The Thermo Fisher Scientific sites have the authority and responsibility to establish and maintain detailed quality system documentation that focuses on the specific needs and expectations of their customers and regulatory requirements. The requirements of this Quality Manual apply to all Thermo Fisher Scientific sites and cover all activities having an impact on product quality and safety.

This manual specifies the minimum Quality System Requirements that suppliers are expected to use in their internal processes to control the quality of the products and services provided to Thermo Fisher Scientific. This manual explains the procedures and the Thermo Fisher Scientific expectations of suppliers that will build and sustain a mutually beneficial relationship. We anticipate and expect that these standardized requirements will improve the quality of products and services provided to Thermo Fisher Scientific and its' customers.

3 SCOPE

The manual applies to all suppliers of materials and services to Thermo Fisher Scientific.

4 REFERENCE

4.1 Supplier Assessment
4.2 Supplier Scorecards
4.3 Master Business Agreement
4.4 Supplier Performance Procedure

5 NEW SUPPLIER EVALUATION

New Thermo Fisher Scientific suppliers will be assessed on their ability to provide quality materials, products or services through one or more of the following: an On-Site Audit, a Supplier Survey, or a Supplier Self-Evaluation. The Thermo Fisher Scientific Supplier Assessment may be used for this purpose. Thermo Fisher Scientific reserves the right to conduct an on-site quality system audit to determine the suppliers' capability of meeting all of Thermo Fisher Scientific requirements. Suppliers capable of meeting Thermo Fisher Scientific requirements may be placed on an Approved Supplier List.

6 SUPPLIERS AND SUPPLIER RATINGS

Some suppliers will be selected to be corporate Suppliers to Thermo Fisher Scientific. Master Business Agreements (MBA's) will be put in place with these suppliers to memorialize those relationships. These suppliers will have their performance monitored and evaluated on a periodic basis for their performance in the areas of Quality, Delivery, Cost Improvement and Business Relationship. The Thermo Fisher Scientific Global Sourcing Supplier Scorecard will be the preferred method used for this purpose. These evaluations will categorize Suppliers into one of the following.

6.1 **Approved Supplier – (Scores maintained between 80 to 100 on the Scorecard)**

The suppliers in this category are truly our preferred suppliers. They have consistently demonstrated the highest scoring on their evaluations. They have demonstrated a commitment to Continuous Improvement practices and have voluntarily come forward to Thermo Fisher Scientific with Quality Improvement and Cost Reduction proposals. They are internally recommended to our R&D and Materials Management departments as the first choice for new business projects as well as to our Engineering and Manufacturing departments for supplier transfer business.

6.2 **Conditionally Approved Supplier – (Scores between 60 to 79 on their assessment)**

The suppliers in this category have attained acceptable ratings on their evaluations. They are expected to improve areas with low scores in order to strive to attain a 'Preferred' rating. They will internally be recommended as a second choice for new or transfer business only when there is not a suitable 'Preferred' supplier available.

6.3 **Unacceptable Supplier – (Scores below 60 on their Assessment/Scorecard)**

The suppliers in this category have received poor ratings in their evaluations. Their performance will be monitored and evaluated closely throughout the term of their relationship with Thermo Fisher Scientific. If their performance does not improve to an Approved level, they may be de-selected from receiving any new business and their existing business may be transferred to other suppliers.

7 SUPPLIER BUSINESS REVIEWS

For our Global Sourcing Suppliers as well as for some of our critical suppliers, Thermo Fisher Scientific will request that regularly scheduled Supplier Business Reviews be prepared and conducted. It is expected that these reviews will be attended by members of the senior management teams both from Thermo Fisher Scientific as well as from the supplier. At a minimum, these reviews will cover past performance by the supplier in the areas of Cost, Quality, Delivery and Service. It is also recommended that other areas such as strategic initiatives, new product introduction topics, new service offerings or improvements also be covered at these reviews.

8 QUALITY SYSTEM

8.1 It is expected that suppliers to Thermo Fisher Scientific will maintain an internal Quality Manual that documents their internal Quality System. Suppliers should be able to demonstrate that they have Management Reviews of their Quality System and are compliant with ISO 9001 or ISO 13485 Quality Management Standards.

8.2 Suppliers must comply with all applicable quality standards and agency requirements as specified by their respective industry, country of manufacture or Thermo Fisher Scientific.

8.3 From time to time, suppliers may by audited by Thermo Fisher Scientific representatives. Such audits may include reviews of the suppliers' Quality System and their compliance to their Quality Manual as well as compliance to all applicable requirements that may be delineated in any contracts or agreements that are in effect between the supplier and Thermo Fisher Scientific.

8.4 All local/national/international standards must be complied with in the areas of human rights, health, safety, environmental, and Corporate Social Responsibility (CSR) governance as well as the Thermo Fisher Scientific Code of Conduct available on our website.

9 TOOLING AND TEST EQUIPMENT

Any fixtures, tooling, test equipment or programs (along with their designs and specifications), that were purchased by Thermo Fisher Scientific and or provided to the supplier for purposes of producing materials or services for Thermo Fisher Scientific, remain the property of Thermo Fisher Scientific and suppliers agree that such items will only be used to produce material or services for Thermo Fisher Scientific unless Thermo Fisher Scientific provides written permission to the contrary. All Thermo Fisher Scientific assets shall be marked as property of Thermo Fisher Scientific (or entities) with applicable identification or asset numbers.

10 DOCUMENT AND DATA CONTROL

10.1 Any Thermo Fisher Scientific drawings, blueprints, specifications or manuals that were supplied by Thermo Fisher Scientific to the supplier for purposes of providing any materials, products or services to Thermo Fisher Scientific remain the property of Thermo Fisher Scientific.

10.2 From time to time, Thermo Fisher Scientific may issue revised drawings, blueprints, specifications or manuals that supersede previous versions. In these instances, the versions of those documents that have been superseded must be marked obsolete, destroyed, or returned to the originating Thermo Fisher Scientific site as specified by Thermo Fisher Scientific.

11 SUB-TIER SUPPLIER CONTROL

11.1 Suppliers are responsible for monitoring and evaluating the quality of material or services that they receive from sub-tier suppliers.

11.2 Upon request from Thermo Fisher Scientific, suppliers shall provide documentation from sub-tier suppliers that document the characteristics and properties of the materials they purchase for use in Thermo Fisher Scientific materials, products or services. These may include; PPAP (Production Part Approval Process) submissions for material, Certificates of Compliance, Certificates of Analysis or Certificates of Service.

11.3 Upon request from Thermo Fisher Scientific, suppliers shall arrange for Thermo Fisher Scientific representatives to visit sub-tier suppliers to review their manufacturing processes and quality management systems.

11.4 In cases where Thermo Fisher Scientific has specified that certain materials or services be purchased from previously approved manufacturers or authorized distributors, it is expected that Suppliers will ensure that all such materials or services used in the production of finished materials or services for Thermo Fisher Scientific are in fact purchased from those approved manufacturers or authorized distributors. Furthermore, the supplier will ensure that these materials and services will conform to Thermo Fisher Scientific specifications and documentation. Thermo Fisher Scientific must approve any changes in suppliers, materials, or processes.

12 CONTROL OF SUPPLIED MATERIALS

12.1 All materials supplied by Thermo Fisher Scientific to its suppliers for purposes of manufacturing products for Thermo Fisher Scientific shall be stored in a manner that maintains the integrity of those materials and their adherence to their specifications. Suppliers are expected to store them in such a manner as to keep them safe from damage or loss.

12.2 Thermo Fisher Scientific owned tools, fixtures and equipment that are provided to suppliers for purposes of producing materials or services for Thermo Fisher Scientific shall be permanently marked as the property of Thermo Fisher Scientific in such a manner that the ownership of each item is easily seen visually. Without prior written approval from Thermo Fisher Scientific, these items may not be used for any other purpose than to produce materials or services for Thermo Fisher Scientific.

12.3 Suppliers must maintain an accurate perpetual inventory of all Thermo Fisher Scientific owned packaging, materials, test equipment or other assets. Suppliers are expected to immediately notify Thermo Fisher Scientific when any of those assets are no longer functional, usable or are in need of repair or replacement.

13 MATERIAL IDENTIFICATION AND TRACEABILITY

13.1 Suppliers shall ensure that all sub-components or materials that are used to manufacture finished materials for Thermo Fisher Scientific are identified according to Thermo Fisher Scientific drawings, specifications, and purchase order terms.

13.2 Unless otherwise specified by Thermo Fisher Scientific, Suppliers shall utilize an effective system, such as unique lot numbers and date stamps, to maintain lot traceability of raw materials. This traceability requirement also applies to materials provided by sub-tier suppliers.

13.3 Suppliers agree to provide Thermo Fisher Scientific with any required certifications of compliance or conformity as may be required by the quality specifications stating that the materials shipped to Thermo Fisher Scientific do, in fact, comply with those specifications.

14 PROCESS CONTROL

General Comments:

14.1 Suppliers will manufacture materials or provide services to Thermo Fisher Scientific as per the requirements specified in the Purchase Orders, Engineering Drawings and Specifications, Statements of Work, Master Business Agreements and Inspection and Process Control Criteria provided by or as agreed to by Thermo Fisher Scientific and the Supplier.

14.2 Suppliers will notify Thermo Fisher Scientific and obtain written approval prior to any deviation from or modification to the raw materials, processes, sub-tier suppliers, or equipment used to manufacture materials or provide services to Thermo Fisher Scientific.

14.3 Suppliers shall have documented procedures for monitoring the process through which materials and services are provided to Thermo Fisher Scientific.

14.4 Suppliers shall identify and plan the production, installation and servicing processes that directly affect the quality of material and services supplied to Thermo Fisher Scientific.

14.5 Suppliers shall ensure that these processes are carried out under controlled

conditions and adhere to the Suppliers' internal Quality System.

For suppliers of Materials (not Services):

14.6 It is expected that suppliers that manufacture materials for Thermo Fisher Scientific will have documented procedures and methods in place to control and measure the processes used to produce those materials.

14.7 The Supplier must have detailed operator instructions and training records for all employees.

14.8 Thermo Fisher Scientific may require submission of Statistical Process Control (SPC) data that was used to control the processing of materials.

14.9 Written notification must be submitted to and approved by Thermo Fisher Scientific prior to the supplier implementing any process, sub-tier supplier or material change that could affect any of the materials, products or services provided to Thermo Fisher Scientific.

14.10 A new Production Part Approval Process (PPAP) may be requested prior to Thermo Fisher Scientific approval of the change for production quantities of material.

14.11 Suppliers shall maintain records of all process changes and their effective dates.

14.12 All records pertaining to process control shall be available for review by Thermo Fisher Scientific upon request.

14.13 The Supplier may be required to provide Thermo Fisher Scientific with copies of their documentation from the following process tools in as much as these tools were used to control the processing of materials, products or services provided to Thermo Fisher Scientific.

14.13.1 Process Flow Chart detailing the process used to produce TMO material

14.13.2 Failure Modes and Effects Analysis (FMEA)

14.13.3 Control Plan

14.13.4 Quality Manual

15 INSPECTION AND TESTING

15.1 Suppliers shall establish and maintain documented procedures for inspection and testing activities to insure that the specified requirements for the material are met. The Control Plan may satisfy this requirement.

15.2 Material shall not be moved to subsequent processes or shipped to Thermo Fisher Scientific until all inspections and tests have been successfully completed and the results documented and authorized to indicate that the materials meet the specifications.

15.3 The Quality Plan should include instructions on inspection or verification of incoming material to its specifications.

15.4 All inspection and test records pertaining to materials for Thermo Fisher Scientific shall be maintained and made available for review by Thermo Fisher Scientific upon request.

15.5 The Supplier's test and inspection process must be operated and maintained in accordance with the most recent ISO standard, if applicable, and/or the Suppliers' internal Quality Manual.

15.6 A test or qualification plan must be provided by the supplier which assures all material specifications are met.

16 CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

16.1 Suppliers shall establish and maintain documented procedures to control, calibrate, and maintain inspection, measuring and test equipment used by the supplier to demonstrate the conformance of materials to the specified requirements.

16.2 Suppliers must maintain calibration records for all inspection and test equipment used to make pass/fail decisions on material manufactured for Thermo Fisher Scientific.

16.3 All calibrations must be current, to the applicable international standards, and all test or inspection equipment tagged or labeled showing current calibration status to a documented schedule.

16.4 The supplier, in conjunction with Thermo Fisher Scientific, shall determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the required accuracy and precision.

17 INSPECTION AND TEST STATUS

17.1 All Thermo Fisher Scientific materials should be tagged, labeled, or otherwise identified showing inspection or test status throughout their processing.

17.2 When required by Thermo Fisher Scientific, additional verification, identification and or certification that the materials meet Thermo Fisher Scientific requirements and specifications shall be provided.

18 CONTROL OF NON-CONFORMING MATERIAL

18.1 Suppliers shall establish and maintain documented procedures to ensure that any product that does not conform to specified requirements is prevented from unintended use. This control shall provide for the identification, documentation, evaluation, segregation and disposition of non-conforming material as well as notification to the function(s) involved with the non-conformance.

18.2 Suppliers shall request a deviation prior to shipping any material that does not meet all Thermo Fisher Scientific specifications and requirements or for material that was produced outside the parameters of an approved process. Shipment of such non-conforming materials will be authorized only after Thermo Fisher Scientific does an evaluation of the deviation and provides the written authorization to the supplier stating that the materials are acceptable for shipment.

18.3 Any rework and or repair which is not part of the approved process for a Thermo Fisher Scientific material must be authorized, in writing, by Thermo Fisher Scientific prior to shipment of that material.

18.4 Suppliers shall contact Thermo Fisher Scientific immediately if it is discovered that suspected non-conforming material may have been shipped to Thermo Fisher Scientific. When defective material is identified at a Thermo Fisher Scientific site, a Discrepant Material Report (DMR) will be sent to the Supplier detailing the nature of the problem along with the identifying part and lot information for that material.

18.5 The supplier shall document the reason for the non-conformance along with their corrective action(s) and return that information to Thermo Fisher Scientific.

18.6 The Supplier shall respond within (2) working days of receipt of the DMR date unless otherwise specified by the Thermo Fisher Scientific site.

18.7 The Supplier's performance rating for the current period will be negatively impacted by each DMR issued if determined to be the supplier's fault.

18.8 The Supplier's performance will also be negatively impacted by failure to respond on or after the response due date.

18.9 Upon notification that nonconforming material has been detected at Thermo Fisher Scientific, the supplier shall initiate contact immediately with Thermo Fisher Scientific to discuss options and disposition of the nonconforming material and issue a Return Material Authorization (RMA).

18.10 The Supplier may choose to have nonconforming material returned to their facility, scrapped at Thermo Fisher Scientific, or, if approved by Thermo Fisher Scientific, arrange for the material to be sorted and/or reworked at the Supplier's expense.

19 CORRECTIVE AND PREVENTIVE ACTION

19.1 When a request for a corrective action report is received by the Supplier from Thermo Fisher Scientific, the response must be documented on corporate form (GS-0001-F-rev) or a site specific form.

19.2 Special attention must be given to identification of the root cause and action to prevent recurrence.

19.3 When a request for a corrective action report is received from Thermo Fisher Scientific a response detailing the short term containment action(s), must be received within (2) working days after being issued unless otherwise specified by the affected site.

19.4 Unless otherwise stated, a complete response detailing the permanent corrective action is due within fourteen (14) working days from the date of issue.

19.5 All responses must be reviewed and approved by Thermo Fisher Scientific.

19.6 If Thermo Fisher Scientific rejects a corrective action response, the Supplier will be required to respond with a different corrective action within five (5) working days from the rejection date.

20 HANDLING, STORAGE, PACKAGING, AND DELIVERY

20.1 Suppliers must have documented procedures to handle, store, package, and ship material in a manner to ensure that it meets all functional and cosmetic specifications upon arrival at Thermo Fisher Scientific.

20.2 All materials provided to Thermo Fisher Scientific must be packaged, labeled, and shipped in accordance with the guidelines set forth in their respective specifications and or their respective Purchase Orders.

20.3 Certificates of Compliance may be required for material provided to Thermo Fisher Scientific.

21 CONTROL OF QUALITY RECORDS

21.1 Suppliers are expected to adhere to the minimum record retention times specified by ISO and their internal Quality Manual for all Thermo Fisher Scientific materials

21.2 Thermo Fisher Scientific may require extended retention times of some quality records. Individual suppliers will be notified accordingly.

22 INTERNAL QUALITY AUDITS

22.1 Suppliers must have and maintain an internal audit program to ensure that all established policies and procedures are being followed

22.2 Internal audit results must be available for review by Thermo Fisher Scientific, as well as any third party audits, such as ISO 9001, 13485 or other appropriate ISO standards.

23 TRAINING

23.1 Suppliers must maintain training records for all employees that process and or make accept/reject decisions on materials, products or services supplied to Thermo Fisher Scientific. Training records must be auditable by Thermo Fisher Scientific.

23.2 Suppliers must have detailed operator instructions for employees that are involved with the manufacturing, testing or qualification of materials, products or services provided to Thermo Fisher Scientific. All operator instructions should be accessible at the operator workstations.

24 HAZARDOUS MATERIALS

Suppliers are responsible for complying with all Federal, State, and Local laws on all materials that are considered “hazardous”. Where applicable, suppliers will furnish a copy of the Material Safety Data Sheet (MSDS) to Thermo Fisher Scientific.

25 REFERENCED MATERIALS

25.1 All referenced documents and associated forms are available for registered users at: https://thermofisherscientific.bravosolution.com/esop/ect/List.do?init=true&reset=true or at

https://thermofisher.sharepoint.com/sites/collaboration/GS-Supplier-Quality/Pages/Supplier-Quality-Procedures.aspx

Revision History

Date	Revised By	New Rev Letter	Comments/Description of Change
	Bob Taylor	B	Original Release
3/22/2013	Mike Pankowski	C	Updated header, section 8.4m and added History Revision page
3/12/2014	Mike Blair	D	Updated rev, changed “Supplier-Partners” to “Strategic Suppliers”
11/17/16	Bob Taylor	E	Updated for ISO requirements
6/5/17	Bob Taylor	F	Removed overview picture page 3, added “assessment” to page 5, added link to sharepoint in 25.1

Title: **Addendum - Supplier Quality Manual, LPD-Asheville Operations**

Rev.: E

	Approvals:	***Date:***
Originator:	Henry Dozier	*8/15/18*
Procurement:	Rebecca Pauley	*8/15/18*
Quality:	Eddie Reavis	*8/15/18*

REVISION PAGE

Rev.	Effective Date	Section(s)	Description
-	5/5/2011	All	New Procedure - Reformatted to be compliant with Asheville's document control procedure
A	6/27/11	All	Added "Purpose", "Scope", and removed signoff page at the end of the procedure. Added reference document "Tooling Management Procedure"
B	11/8/11	9, 12.4, 15.7	Added verbiage pointing to "Tooling Management Procedure" in sections 9 & 12. Added statement to section 15 to address product verification at supplier premises.
C	8/24/15	14.20, 14.23, 20.6, 25	Added requirements to level 1 PPAP. Reworded statement about SQE/SDE roles for supplier PPAP submittal. Added statement about special packaging instructions for supplier issued RMA's. Updated reference documents.
D	5/11/17	14.20 25, 26	Swopped level 3 and level 4 PPAP requirements. Added responsibility matrices section. Removed document attachments and added link to Supplier Portal.
E	8/15/18	9, 12, 26 14.23 25 26 Throughout	Removed reference to Tooling/Equipment Procedure Removed Supplier Development Engineer Removed OEM, CM, and Service Providers from matrix section Updated link to Supplier Portal Replaced "Sourcing" with "Procurement"

Title: Addendum - Supplier Quality Manual, LPD-Asheville Operations

Rev.: E

PURPOSE

The purpose of this addendum is to supplement the Supplier Quality Manual by providing additional quality requirements and expectations, which apply specifically to suppliers and subcontractors that provide products, parts, accessories, and services to the Asheville site.

SCOPE

The addendum is not intended to replace the language contained in any individual agreements, contracts or specifications, but is intended to convey the minimum quality requirements of the Asheville site.

4 REFERENCE

4.5 Document Attachments (Section 25)

5 NEW SUPPLIER EVALUATION

There is no addendum to this section at this time.

6 SUPPLIER-PARTNERS AND SUPPLIER RATINGS

There is no addendum to this section at this time.

7 SUPPLIER BUSINESS REVIEWS

There is no addendum to this section at this time.

8 QUALITY SYSTEM

8.5 In the event a supplier's agency or quality registration status changes or is suspended, the supplier will notify Thermo Fisher and locations to which product is supplied, within five (5) business days. In the event that the supplier name changes, changes in ownership, facility changes or changes in senior Quality management may subject Supplier's Quality System to reevaluation by Thermo Fisher. Supplier will notify Thermo Fisher Procurement of any of the aforementioned changes in writing.

9 TOOLING AND TEST EQUIPMENT

There is no addendum to this section at this time.

10 DOCUMENT AND DATA CONTROL

There is no addendum to this section at this time.

11 SUB-TIER SUPPLIER CONTROL

There is no addendum to this section at this time.

12 CONTROL OF SUPPLIED MATERIALS

There is no addendum to this section at this time.

13 MATERIAL IDENTIFICATION AND TRACEABILITY

13.4 Suppliers will follow the lot code traceability requirements for all parts supplied as indicated below:

1. All finished goods (assemblies or components) will have identification of:
    - A) Thermo Fisher Scientific part number
    - B) Supplier code, identification, or nomenclature as applicable
    - C) Manufacturing date, lot code information, or serial number
    - D) Thermo Fisher Scientific drawing revision level when noted on Thermo Fisher Scientific drawings or specifications
2. For barcode labeling as required by Thermo Fisher Scientific drawings or specifications, the information that will be bar coded for identification (in addition to human readable text) is as follows:
    - A) Part number
    - B) Manufacturing date, lot code information, or serial number
3. Bar coding will meet following requirements:
    - A) Symbology is code 128 (any subtype)
    - B) Barcode minimum height= 0.250 inch
    - C) Minimum module width= 0.010 inch

13.5 Suppliers agree to apply labels to the packaging of parts supplied to Thermo Fisher Scientific in accordance with the requirements as described in the Supplier Labeling Requirements procedure attached.

14 PROCESS CONTROL

14.14 When the supplier becomes aware of any facts suggesting the product to be shipped does not conform to Thermo Engineering requirements or standards, and does not pose a safety, fit, form, or functional problem, the supplier will notify Procurement in writing and may request a deviation. The request for deviation will only be used in cases of emergency where there is a significant risk of disruption to the supply chain that can adversely impact Thermo Fisher Scientific. In all cases, the supplier is expected to use this option in cases of last resort.

14.15 The supplier will submit a deviation request to the Procurement department by using the Supplier Part Deviation Request form. The request will be made and approved prior to the shipment of discrepant material. All deviated product will be clearly identified. If the deviation is not approved, the supplier may not release deviated product. Unapproved product will be rejected.

14.16 For new and current production parts, the Production Part Approval Process (PPAP) will apply for all materials used in Thermo Fisher Scientific products and will be submitted prior to the

first production shipment. The only exceptions to this are Pre-Production or Prototype samples ordered prior to the first production shipment for the purpose of supporting Engineering Trials, Line Trials, Tooling Trials or Equipment "Run-Off". For all PPAP submissions, the supplier will use the Supplier Part Approval Request form.

14.17 PPAP and First Article Inspection (FAI) samples will be submitted for approval under the following conditions:

- When a new Thermo Fisher Scientific part or product requires manufacture.
- When a part needs to be modified because of a Thermo Fisher Scientific engineering change.
- When a different material is used to make the part than was previously approved.
- When new, repaired or modified tools (except perishable tools), dies, molds, etc., are used in production. *Note: This is not meant to be confused with normal maintenance, repair, or replacement of parts, etc., for which no change in performance is to be expected and post repair verification methods have been established. It is also not meant to be confused with standard tools (new or repaired), such as standard measuring devices, drivers (manual or power), etc.*
- When the supplier makes any change to the production process that can affect fit, form, or function of product supplied. This includes any change in test/inspection method as this change type can have an impact on acceptance criteria.
- When tooling and equipment is transferred to a different manufacturing location or an additional manufacturing location will be used to make the part.
- When tooling is transferred from a previous supplier.
- When the tooling has been idle for more than 12 months.
- Correction of discrepancy on a previously submitted part or product

14.18 In addition to copies of the documentation requirements listed in section 14.13, the following documentation may be required as well:

- Supplier Part Approval Request
- Engineering Change Documents, if any
- Customer Engineering approval, if required
- Measurement System Analysis Studies
- Dimensional Results
- Material Test Results
- Performance Test Results
- Initial Process Capability Studies

- Material Certification
- Documentation for approval of sub-tier suppliers
- Engineering Change Approval procedure
- Appearance Approval Request, if applicable

14.19 The PPAP submission will be submitted on the attached Thermo Fisher Scientific forms. With the exception of the Supplier Part Approval Request and Supplier Part Deviation Request forms, suppliers may use their own forms for the submission items provided the reported information is the same as required on the Thermo Fisher Scientific forms. For questions concerning statistical studies required for submission, the supplier is advised to consult with the assigned Supplier Quality Engineer or Supplier Development Engineer.

14.20 The requirements for PPAP submission can be 1 of 5 levels. The standard submission requirement is a Level 4. These levels and their requirements are as follows:

- Level 1
  - Supplier Part Approval Request
  - Drawing acknowledgement and acceptance
  - Manufacturing Feasibility Analysis (MFA)
  - Certificate of Conformance (COC)
  - Appearance approval request, if applicable.
- Level 2:
  - Supplier Part Approval Request
  - FAI samples with Thermo Fisher Scientific drawing
  - Dimensional data - A full dimensional layout or partial dimensional results on critical characteristics may be required.
  - Appearance approval request, if applicable.
- Level 3: Full PPAP submission package
  - Supplier Part Approval Request
  - Engineering Change Documents, if any
  - Customer Engineering approval, if required
  - FAI samples with Thermo Fisher Scientific drawing
  - Dimensional data - A full dimensional layout or partial dimensional results on critical characteristics may be required.

- Process Flow Chart detailing the process used to produce Thermo Fisher Scientific material
- Failure Modes and Effects Analysis (FMEA)
- Control Plan
- Quality Manual
- Engineering Change Approval Procedure
- Measurement System Analysis Studies
- Records of Material / Performance Test Results
- Initial Process Capability Studies
  - *Note: Minimum acceptable result for Cpk or Ppk is 1.33, while 1.67 or greater is preferred. Any results less than 1.33 will result in PPAP rejection unless supplier can provide a corrective action plan and/or demonstrate in control plan that 100% inspection will prevent nonconforming product from escaping the process.*
- Material Certification
  - *Note: For Material Certification, a copy of the actual mill certification or lab results are acceptable provided the certification indicates the specification and the actual results obtained.*
- Appearance Approval Request, if applicable
- Documentation for approval of sub-tier suppliers

- Level 4:
  - Supplier Part Approval Request
  - FAI samples with Thermo Fisher Scientific drawing
  - Dimensional data - A full dimensional layout or partial dimensional results on critical characteristics may be required.
  - Material Test Results
  - Performance Test Results
  - Appearance approval request, if applicable.

- Level 5:
  - Supplier Part Approval Request
  - Any of the requirements from the Levels 1 - 4 or additional requirements as defined by Thermo Fisher Scientific.

14.21 The supplier is responsible for submitting FAI samples as part of the PPAP submission as described above. Furthermore, the supplier is responsibility for performing their own measurement and testing of these samples prior to submitting to Thermo Fisher Scientific. The samples will be numbered and submitted along with the measurement and test results to the assigned Supplier Quality Engineer or Supplier Development Engineer. The following additional requirements apply for FAI samples submitted:

- Parts submitted for PPAP Approval will be taken from production intent tooling and processes.
- Parts submitted for PPAP Approval will be taken from a significant production run of at least 300 pieces for high volume suppliers, or 30 pieces for low volume suppliers. Any exceptions to this rule will have prior approval by the Supplier Quality Engineer or Supplier Development Engineer.
- For all characteristics, the measurement results of five (5) samples minimum are required or as otherwise directed by the Supplier Quality Engineer or Supplier Development Engineer.
- All dimensions and notes on the drawing (excluding reference dimensions) will be measured and recorded as variable data on the inspection report for each sample. This data will correspond to the numbered samples from which they were taken.
- All data will be reported in the unit of measure shown on the drawing.
- Parts from multi-cavity molds or dies will be approved individually.

14.22 Quality Assurance may inspect the FAI samples as part of the approval process, if required. In such cases, reviews by other functions such as Design Engineering, Manufacturing Engineering, Supplier Quality Engineering, Supplier Development Engineering and Marketing may be performed. If the provided samples are not approved, the Procurement department will notify the supplier of such status, and request corrective action and PPAP resubmission, as applicable.

14.23 The PPAP submission and documentation including FAI samples are to be sent to the attention of the Supplier Quality Engineer. Each submission will include the appropriate documentation as required by the submission level indicated on the Supplier Part Approval Request form. PPAP documentation will be submitted in binders with a tab for each section as required by the submission level. A copy of the PPAP documentation package will be included with the shipment or mailed separately in advance of this shipment. Electronic copies can be submitted as back-up only.

14.24 When shipping samples, the suppliers will identify FAI, Pre-Production, and Prototype samples with FAI labels, which can be printed on standard “orange” colored 8”x11” print paper. These labels are to be attached on at least two adjacent sides of the shipping container. Reference the FAI Label Template attached.

14.25 In the event a supplier fails to provide the proper labeling and shipping requirements as described above, the parts can inadvertently go directly to the warehouse resulting in approval delays and other undesirable conditions. Samples that do not comply with these requirements will be considered nonconforming, rejected, and corrective action may be required.

15 INSPECTION AND TESTING

15.7 At this time Thermo Fisher does not perform product verification at suppliers' premises as standard practice, other than that which may be required for First Article sample submission as described in the section "Process Control" of this manual. Should the need be identified through Management Review or Quality Planning for additional product verification measures, the designated personnel will develop, document and implement suitable procedures. Thermo Fisher considers product verification of the products procured from its suppliers to be the primary responsibility of each supplier.

16 CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

16.5 Appropriate statistical studies will be conducted to analyze the variation present in the results of each type of measuring and test equipment system. This requirement applies to measurement systems that control the outputs of the dimensional and functional characteristics as indicated in the supplier's process control plan.

16.6 The analytical methods and acceptance criteria used for qualifying the measuring and test equipment system will be in accordance with Quality and Manufacturing Engineering norms. Examples of these methods include bias, linearity, stability, and repeatability and reproducibility studies.

17 INSPECTION AND TEST STATUS

There is no addendum to this section at this time.

18 CONTROL OF NON-CONFORMING MATERIAL

18.10 Thermo Fisher Scientific will issue a Return Material Authorization Request (RMA) form and return the defective material to the supplier at the supplier's expense. Maximum time allowed for completion of this process is 24 hours from the time of notification. The RMA will be received by Thermo Fisher Scientific within 72 hours or the material will be automatically returned.

18.11 The supplier will analyze parts returned from Thermo Fisher Scientific. Records of these analyses will be kept and made available upon request. The supplier will perform effective analysis and where appropriate, initiate corrective action and process changes to prevent recurrence. In cases where such analyses show the nonconformity not to be the fault of the supplier, the supplier will notify Thermo Fisher Scientific in writing within 14-days from receipt of the parts. This notification ensures that an investigation occurs between the supplier and Thermo Fisher Scientific, and corrections are made where applicable.

18.12 For product returned to the supplier as "suspect", suppliers may be required to sort and/or rework discrepant material with the proper equipment (gages, fixtures, etc.). Immediate action may be required upon notification in order to avoid disruption of production. In such cases, Thermo Fisher Scientific will sort only the quantity needed to support immediate production needs.

18.13 In cases of supplier sort or rework, all sort plans and rework methods will be submitted to and approved by the assigned Supplier Quality Engineer prior to the start of the sort or rework process.

18.14 Due to circumstances of timing or capability, suppliers may be required to arrange for off-site third party sorting at the suppliers' expense. Thermo Fisher Scientific will not coordinate this activity, but can assist the supplier in identifying local sources that provide this service.

18.15 Suppliers will provide "certified replacement" material when possible and coordinate this activity with Thermo Fisher Scientific Procurement department.

18.16 Suppliers will not be allowed to sort any Thermo Fisher Scientific final assembly and/or finished goods.

18.17 When the supplier becomes aware of "suspect" product that has escaped from the supplier's and/or the sub-tier supplier's facility, the supplier will notify Thermo Fisher Scientific in writing within 24 hours. The notification will at the minimum contain the following information:

- Supplier Name
- Description of the defect
- All affected part numbers
- P.O. number(s)
- Quantities and Dates delivered
- Manufacturing date
- Notification to Thermo Fisher Procurement representative
- Method Discovery (discovered by supplier insp., TFS audit etc)
- Traceability information
- Attachment of all test/inspection data
- Information regarding rejection and the impoundment of all work-in-process Notifications of escape will be sent via email to Thermo Fisher Procurement and/or the Supplier Quality Engineer.

19 CORRECTIVE AND PREVENTIVE ACTION

19.7 For all containment actions and corrective actions taken by the supplier, the supplier will document in the SCAR form the initial ship dates, lot numbers, and/or serial numbers, so that traceability can be established from these actions.

19.8 For all product impacted from the short-term containment action(s) taken, the supplier will mark the product and label each packaging/container in a manner that indicates to Thermo Fisher Scientific that it is "Certified" as good product with respect to the problem as reported in the corrective action report. This includes all product shipped until a corrective action is implemented and verified as effective. Certified material will be identified with labeling to state that it is "Certified" for the problem condition reported. This label identification will be clearly visible and securely attached on at least two adjacent sides of the package/container of the material sorted or reworked. Each skid and/or package will be identified accordingly.

19.9 Before marking of the product as an additional method to indicate that it is "Certified", the supplier is required to get prior approval from Thermo Fisher Scientific in order to avoid marking the product in a location that would adversely impact the function of the product or would be unacceptable to the final customer.

19.10 Depending on the risk impact assessed and the degree of disruption to production, Thermo Fisher Scientific may seek financial recovery from suppliers resulting from suppliers' poor Quality or Delivery performance. Thermo Fisher Scientific may charge costs back to suppliers for any activity performed as it relates to such performance. The following activities apply:

- Loss of Production / Downtime
- Sort, Inspection, Rework (Performed by Thermo)
- Scrap - $ Cost of Inventory (Raw, WIP, FG)
- Logistics and Freight, including Premium Freight - $ Cost incurred by Thermo Fisher Scientific
- Travel and Expenses - $ Cost incurred by Thermo Fisher Scientific
- Thermo Fisher Scientific Customer Costs - $ Cost incurred by Thermo Fisher Scientific

20 HANDLING, STORAGE, PACKAGING, AND DELIVERY

20.4 No additional charge will be made to Thermo Fisher Scientific for containers, packaging, or transport unless expressly agreed to by Thermo Fisher Scientific in writing. The suppliers will be responsible for all damage and/or contamination to parts resulting from a failure to pack, and load properly and securely as appropriate for the parts delivered.

20.5 When shipping parts to Thermo Fisher Scientific, suppliers will follow the instructions as indicated in the Supplier Routing letter attached.

20.6 For parts to be returned to the supplier, the supplier is responsible for providing any special packaging instructions to Thermo Fisher Scientific at the time of RMA issuance. Otherwise, there is no guarantee that the parts will be packaged as originally shipped to Thermo Fisher Scientific or in a manner deemed suitable by the supplier. Thermo Fisher Scientific will not be held liable for any freight or material costs incurred due to a lack of such instructions.

21 CONTROL OF QUALITY RECORDS

There is no addendum to this section at this time.

22 INTERNAL QUALITY AUDITS

There is no addendum to this section at this time.

23 TRAINING

There is no addendum to this section at this time.

24 HAZARDOUS MATERIALS

There is no addendum to this section at this time.

25 RESPONSIBILITY MATRICES

Below are the standard responsibilities between Thermo Fisher Scientific and the supplier of components/materials to Asheville manufacturing operations. These responsibilities are standard and do not supersede specific contractual arrangements.

Responsibility Matrices
LEGEND: R - Responsible; X - Not responsible but may support as required

Component/Material Supplier

Item	Supplier	Thermo Fisher Scientific
Product Specifications (Supplier Owned)	R (component)	X
Product Specifications (Supplier Does Not Own)	X	R
Production Process Specifications	R (component)	X
Packaging Specifications	R (component)	X

Supplier Evaluation/Audits	R (sub-tier)	R
Installation Records/Tracability (End Customer)	X	R
Lot/Piece Tracability (as applicable)	R (component)	X
Supplier CAPA	R	X
Field Data Monitoring/Feedback (End Customer)	R (component)	R (end customer)
Field Alert/Recall	R (notification)	R (end customer)

26 DOCUMENTS – The documents listed below can be found on the Supplier Portal at https://ledsupplierportal.thermofisher.com/

Document No.	Document Name
Not Applicable (Letter)	Supplier Routing
PP005	Supplier Labeling Requirements
SP002	Return Material Authorization Request
FPC023	Supplier Part Approval Request
FPC022	Supplier Part Deviation Request
FPC024	FAI Label Template
FPC015	Supplier Dimensional Measurement Results
FPC016	Supplier Material Test Results
FPC017	Supplier Performance Test Results
FPC018	Supplier Appearance Approval Request

FPC019	Supplier Process Flow Diagram
FPC020	Supplier FMEA
FPC021	Supplier Control Plan

Note:
Suppliers can obtain additional reference publications related to PPAP and Advance Quality Product Planning (APQP) from the Automotive Industry Action Group (AIAG). These publications should be treated as resources to establish, implement, and maintain an effective quality system and assist the supplier in meeting the requirements set forth in this manual.

The following documents are available:

- *Advanced Quality Product Planning and Control Manual (APQP)*
- *Potential Failure Mode and Effects Analysis (FMEA)*
- *Measurement Systems Analysis Reference Manual (MSA)*
- *Fundamental Statistical Process Control (SPC) Reference Manual*
- *Production Part Approval Process (PPAP)*
- *Quality Systems Assessment (QSA)*

The documents can be purchased from:

Automotive Industry Action Group
26200 Lahser Road, Suite 200
Southfield, MI 48034
Phone: (248) 358-3570
Fax: (248) 358-3253