

TITLE: Tooling Management Procedure

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1. Purpose

The purpose of this procedure is to clearly define the tooling management requirements and process for suppliers delivering parts or performing services to Thermo Fisher Scientific (TFS), Asheville, NC. This procedure defines the supplier's responsibility for design, fabrication, and handling of TFS owned tooling. It also establishes requirements for records and reports associated with the maintenance and disposition of TFS tooling.

2. Scope

- This procedure applies to all direct material and service suppliers. It applies to all tooling either furnished to, fabricated or procured by the suppliers under a TFS purchase order or other authorizing document, and includes tooling located at a supplier's lower tier supplier.
- Expendable tools, shop equipment, and capital tooling are specifically excluded from this procedure.

3. Supplier Compliance

- a. All tooling including the designs and specifications that were purchased by TFS and/or provided to the supplier for the purpose of producing product or performing services for TFS remain the property of TFS.
- b. Suppliers are to only use TFS tooling for producing product and performing services for TFS. Any other use is strictly prohibited and can only be done with the written consent of TFS.
- c. TFS has the right to remove all and/or any tooling at the Supplier at any time upon verbal and written notices which may includes electronic media.
- d. Suppliers are responsible for meeting all the requirements defined within this procedure. Failure to do so may result in the removal of all tooling from the supplier's premises.
- e. The Suppliers are expected to meet all on-time delivery from tooling owned by TFS under normal use.
- f. Suppliers are responsible for achieving 100% part conformance to TFS drawings and specifications. For its achievement, suppliers must ensure that the tooling is inspected to applicable data (engineering data, engineering drawings, master layouts, tool design, control tool, etc.) as specified in the purchase order prior to release to production. It is understood that TFS owns all design drawings and specifications. TFS will be forward a copy of all tooling design drawings per guidelines of this procedure.
- g. In the event that the supplier recommends any change to the print / tooling, a TFS, ECR, must be
- h. Suppliers are responsible for pursuing continuous improvement activities that will support and ensure flawless tooling reliability.
- i. Failure to meet these requirements may result in the loss of existing or future business with TFS. Any and all costs associated with the supplier's failure to comply with this procedure will be the responsibility of the supplier.
- j. TFS will be allowed to visit the supplier for full process and tooling audits at TFS discretion. TFS will notify the supplier of such audits with three working days from the time of audit.

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4. References

Supplier Quality Manual	GS-002-P-B
Addendum Supplier Quality Manual – Asheville	
Metal Forming Checksheet Form	FPC025
Test Tooling Checksheet Form	FPC026
Plastic Molding Checksheet Form	FPC027
Supplier’s Acceptance Management Agreement	FPC028
Supplier Master Tooling/Fixture List	FPC029
Manufacturing Feasibility Analysis form	FPC030
Part Deviation Request	FPC022
Supplier Part Approval Request	FPC023

5. Definitions

- 5.1 Tooling/Tools - All test equipment, test fixtures, measuring devices, molds, jigs, dies, patterns, taps, gages, templates and other manufacturing aids made for and limited to the production of particular detail parts and assemblies for TFS.
- 5.2 PCBA - Printed Circuit Board Assembly
- 5.3 Test Equipment - A single or multipurpose test unit designed, developed, fabricated, modified, or procured to TFS specifications. Also a single or multipurpose test unit used to develop, produce, test, service, or measure parts. It may consist of a single item or an assembly, including standard or general purpose items or components that are interconnected and inter-dependent, so as to become new functional entity.
- 5.4 Expendable Tooling - These tools consist of catalogue items readily available on the open market, which, because of their size and nature are considered expendable. Drills, reamers, snap gauges, electrodes and all types of cutting tools are considered expendable tools, even though they are altered for production purposes and may be special in nature.
- 5.5 Shop Equipment and Capital Tools - These tools include supplier owned plant equipment such as: machines, motors, cranes, etc. Suppliers shall utilize any/all supplier owned shop equipment, which is not to be included in tooling quotations for support of production.
- 5.6 ECR - Engineering Change Order
- 5.7 DC - Document Control

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6. Manufacturing Feasibility Considerations

- 6.1 TFS has considered control questions, although not intended to be all-inclusive, for suppliers to perform a feasibility evaluation. The drawings and/or specifications provided to the supplier must be used as a basis for analyzing its ability to meet all specified requirements from TFS.
- 6.2 The Manufacturing Feasibility Analysis Form FPC030 is required to be completed by the supplier to help TFS understand the extent of its process capability and feasibility to meet the drawings and/or specifications. The areas of the feasibility evaluation will include, but not limited to the following areas:
- 1) Engineering
 - 2) Manufacturing
 - 3) Quality / Inspection
 - 4) Capacity Planning
 - 5) Cost Analysis
 - 6) Statistical
- 6.2 The Manufacturing Feasibility Analysis Form shall be published and sent to TFS Sourcing when new business, new tooling, tooling relocation or tooling transfer is confirmed and prior to commencement of production.

7. Tooling Packaging and Shipping

- 7.1 TFS and the supplier will agree upon the packaging specifications for the tooling during the tool development phase. The agreed upon specification will be detailed on the tooling purchase order.
- 7.2 It is the supplier's responsibility to provide adequate packaging to protect TFS tooling during shipping.
- The basic requirements for packaging and shipment will include:
 - 1) Packaging shall be sufficiently robust to protect the tooling. The packaging must be robust enough to prevent damage or contamination during tooling shipment.
 - 2) TFS may require an independent evaluation of the tooling after shipment for validation purposes when damage is suspected or found after shipment from the supplier's premises.
 - 3) All packaging must be labeled as specified for all tooling delivered.
 - 4) There shall be only one part number for each tool and only one part number on each shipping container unless otherwise agreed upon with TFS.
 - 5) Suppliers are responsible for providing all shipping and release documents in a timely manner as required. Any failure to do so may result in fees and expedited freight cost

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incurred on the part of the supplier.

- 7.3 In the event that any of these parameters are not met the tooling may be rejected upon delivery and shipping cost will be the responsibility of the supplier at the discretion of TFS.

8. Tooling Storage:

- 8.1 Suppliers are responsible for the safe storage of the fixtures, tooling, and test equipment. This responsibility extends to damage and risk of loss from the time it is delivered to supplier until it is returned to TFS.
- 8.2 All tooling components and parts supplied by TFS to its suppliers for purposes of manufacturing products for TFS 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.

9. New Tooling

- 9.1 TFS highly recommends that the production supplier be integrated into the design process for new tooling. TFS requires the production supplier to manage new tooling projects. This would include the development of prototype tooling and prototype components. This involvement allows for a smoother introduction of production tooling at the supplier. It will also help enable suppliers to consistently produce high quality parts while meeting the desired process capabilities. This project management requirement includes the development of a formal project plan.
- 9.2 All parts produced from new production tooling must go through the required qualification process, including PPAP as directed by the TFS Supplier Engineering Department. Modifications to the tool design that occur during or after the qualification process may require parts to go through a portion or all of the qualification process a second time. Suppliers are encouraged to raise the issue of potential different requirements (i.e. cosmetic) for TFS parts and accessories during this initial qualification process.
- 9.3 These project plans are expected to be updated and delivered to the designated representatives at TFS Sourcing on a regular basis, which will be predetermined by TFS. TFS Engineering, Quality, and Sourcing Departments must be notified immediately of any major changes to the original project plan that may impact the quality or timing of the new tool.

10. Tooling Identification and Traceability

- 10.1 Tooling identification and traceability are essential requirements for proper management of TFS tooling. The tooling shall be identified to include the part number, serial number, detachable components, and ownership.
- 10.2 If the tool requires modification as a result of purchase order change, then the tool identification must reflect

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revision A, B, etc., as applicable a TFS Sourcing will be notified prior to replacement.

- 10.3 The tooling must be properly named and properly tagged with a TFS identification number supplied by TFS. Whenever practical, tools shall be identified by means of a metal tool identification tag to be affixed upon the tool.
- 10.4 If tool tags are impractical because of the design and/or material, tooling identification shall be accomplished as described below.
- 10.4.1 Metal tools shall be identified by acid etching, electro-engraving, vibropeening, steel stamping, laser etching or any other method that will permanently identify, but not damage the tools.
- 10.4.2 Wood and plastic tools shall be identified by impressing, stenciling, or stamping. Tools too small for any of the above methods shall be boxed and/or chained/affixed to a tool tag to ensure their proper identity.
- 10.4.3 Regardless of identification method applied, suppliers must ensure that the identification number is maintained in good condition at all times, and will not be removed or altered in anyway once affixed to the tooling. Should the identification number become damaged or illegible in any respect, the supplier agrees to immediately notifying TFS and replacing the damaged tag with a new one from TFS.
- 10.4.4 The name, identification number, a photo of each tool together with the part it produces must be taken and included for all tools that are documented on the Supplier Tooling/Fixture Master List, FPC029 and sent to Sourcing by June 30, of each calendar year.
- 10.4.5 The production tooling payment on any new sourcing awards is contingent upon that all tooling is tag in accordance with this procedure. Once the supplier submits the digital pictures of the tooling with clear permanent identification that states that this tooling is 'Property of TFS' and shows our tooling order number...only then payment is released to the supplier for the tooling cost

11. Tool Maintenance and Reporting

- 11.1 Suppliers are responsible for performing all maintenance work, repairs and component replacements as necessary to ensure tooling remains in good working condition and suitable for its intended use.
- 11.2 Any maintenance required that exceeds what is considered to be normal wear and tear of the tooling, any component replacements, and repair work must be documented and reported to TFS Sourcing immediately upon discovery. Such work shall have prior approval from TFS before performed.

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- 11.3 Suppliers must have effective systems in place for completing proper maintenance on TFS tooling at periodic intervals so that optimal tooling performance and conditioning are ensured as set forth prior to approval by TFS.
- 11.4 When the tooling is not in use or is taken out for service, TFS requires that it be stored in a manner that maintains its integrity, and does not put it at risk for possible loss or damage.
- 11.5 Suppliers shall report to TFS Sourcing on an annual basis regarding the condition of the tooling, its remaining life expectancy and should be used in the quality production of TFS production parts. The appropriate and required forms for tracking the current condition of the tooling are an integrate part of this procedure and are listed in this section below. Although these forms are self explanatory for data entry purposes, the TFS Supplier Quality Department is available for guidance in completing the form(s) as needed.
- There are three forms that are available and each form is representative of the different types of tooling that can apply. The forms are as follows:
- 1) Metal Forming Checksheet Form, FPC025
 - 2) Test Tooling Checksheet Form, FPC026
 - 3) Plastic Molding Checksheet Form, FPC027
- 11.6 When a supplier is notified by TFS of a part problem that may relate to the tooling, a team must be assembled by the supplier to determine root cause and corrective action. TFS recommends suppliers use the industry standard Global 8-D problem solving methodology and submit results to TFS upon completion.

12. Tooling Calibration (Test Equipment & Measuring Devices)

- 12.1 TFS requires calibration to be performed on test equipment and measuring devices in accordance with the specification provided from TFS or the original equipment manufacturer.
- 12.2 All calibration results will be documented on the supplier's internal calibration document(s) and forwarded to the designated TFS Sourcing representative at the predetermined calibration interval established by TFS Sourcing for the equipment.
- 12.3 Calibration reports should include at the minimum the following data:
- 1) Manufacturer
 - 2) Tool Name
 - 3) Serial Number
 - 4) Tool ID Number
 - 5) Calibration Cycle
 - 6) Last Calibration Date

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- 7) Calibration Due Date
- 8) Initial of Person Performing the Calibration

13. Tooling Changes

- 13.1 Any change to the tooling, the process where the tooling is used, or the physical location of the tooling **MUST** have prior approval by TFS before implementation of the change. Furthermore, TFS shall be notified immediately and in advance once the supplier has made firm plans to make such changes. All proposed changes must be documented on an Form FPC022 (Supplier Part Deviation Request) and Form FPC023 (Supplier Part Approval Request) for TFS, review prior to any changes or temporary changes that may affect any drawing, tooling or any documentation that may pertinent to the tooling production concerning TFS. Both these forms will be provided by TFS upon request.
- 13.2 Failure to notify TFS in advance or failure to obtain prior approval can result in immediate containment of parts produced and 100% inspection of such at the supplier’s expense. Further consequences may include “New Business Hold” and/or the immediate loss of the existing business.

14. Tooling Transfers

- 14.1 Any tooling that is being transferred should be done so by ensuring the following:
 - All tooling shall be identified as specified in the Tooling Identification and Traceability section of this procedure.
 - The transfer of all related documentation and software available including drawings, specifications, recent run records, and maintenance records, etc.
 - The transfer of all TFS owned measuring tools, gauges, electronic measuring devices, spare parts, paint chip coupons, etc.
- 14.2 In cases where the tooling is transferred from one supplier to another supplier, the transferee must complete the Manufacturing Feasibility Analysis form FPC030 as described in section Manufacturing Feasibility Considerations of this procedure.

15. Tooling Not In Service

- 15.1 When the tooling is not in use or is taken out of service, TFS requires that it be stored in a manner that maintains its integrity, and does not put it at risk for possible loss or damage.
- 15.2 TFS considers it’s tooling to be obsolete when:
 - 15.2a The tooling is no longer capable of producing parts that consistently meet the required quality standards within acceptable process parameters or
 - 15.2b The product it is producing is considered obsolete.
- 15.3 All potential repair options must be exhausted before the production tool can be deemed unusable or obsolete. TFS only considers a product to be obsolete if there is no potential for future demand, including service requirements, for that particular product.

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- 15.4 Once a tool has been determined obsolete, the supplier must contact the appropriate TFS Sourcing representative for further direction regarding the disposition of the tool. The supplier must also notify TFS if there are any components that can be salvaged from the tool. TFS will then determine whether to destroy, store, or return the tooling to TFS.

16. Tooling and Product Verification

- 16.1 TFS Sourcing representative shall be afforded the right to verify at the supplier’s premises that the TFS tooling conforms to requirements specified by TFS. Such verification shall not be used by the supplier as evidence of effective quality control. Under normal operating conditions of the tooling, the control of quality for the parts produced from the tooling is the sole responsibility of the supplier.
- 16.2 Verification by TFS shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer. Upon request, the supplier is required to provide verification that product from the tooling being produced meets all print specifications and requirements.

17. Records

- 17.1 Suppliers shall maintain adequate records for all TFS tooling in accordance with the supplier’s Quality Management System. It is necessary for the records to reflect the following:
- Ownership and contract (purchase order number) under which the tools are fabricated
 - Part number and serial number
 - Nomenclature and description
 - Location of tools
 - Rework and/or TFS disposition authority for tools no longer in the supplier’s possession
- 17.2 Suppliers shall maintain current tool designs, schematic drawings, sketches and photographs used in the fabrication, testing or calibration of tooling for future references and/or revisions.
- 17.3 Tool manufacturing tolerances will be shown on the tool design. Disposition of this data will be made at the same time the disposition of the related tool is provided.
- 17.4 TFS – Asheville will maintain the following records:

Record	Retention	Location	Index Method
Metal Forming Checksheet FPC025	7 yrs	DC	Electronic
Test Tooling Checksheet FPC026	7 yrs	DC	Electronic
Plastic Molding Checksheet FPC027	7 yrs	DC	Electronic

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Record	Retention	Location	Index Method
Manufacturing Feasibility Analysis FPC030	7 yrs	DC	Electronic
Part Deviation Request FPC022	7 yrs	DC	Electronic
Supplier Part Approval Request FPC023	7 yrs	DC	Electronic

18. SUPPLIER ACCEPTANCE AND AGREEMENT

- 18.1 This procedure shall govern the possession and use of all TFS owned tooling. For the tooling that is now in the possession by the supplier or that may be placed in the possession of the supplier is subject to the requirement set forth in this procedure. All TFS tooling must be listed by the supplier on the Supplier Tooling/Fixture Master List FPC029, and signed by authorized personnel.
- 18.2 Also, the Supplier’s Acceptance and Management Agreement Form FPC028 will accompany Form FPC029, and will serve as the supplier’s agreement to and acceptance of this procedure.

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