

EXTERNAL PROVIDER/SUPPLIER AND SUBTIER SUPPLIER REQUIREMENTS

Acceptance of a Purchase Order from ThermoFusion, Inc binds the Supplier to the Terms and Conditions listed in the Purchase Order and the requirements listed in this document.

- 1. Enter this order in accordance with the prices, terms, delivery method, and specifications listed above.
- 2. Send all correspondence to: ap@thermo-fusion.com
- 3. Please notify us immediately if you are unable to ship as specified and by due date.

The Supplier is not authorized to outsource any portion of the Purchase Order requirements unless specifically authorized by ThermoFusion, Inc (TFI) and must flow down these requirements to any sub-tier Suppliers.

- A. **DOCUMENTS**: TFI will communicate to the Supplier the requirements for processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions) in the form of a purchase order or supporting documentation. It is the Supplier's responsibility to flow down those requirements to sub-tier Supplier;
- B. <u>APPROVALS</u>: Supplier or sub-tier Supplier must provide a statement of conformance for the approval of:
 - products and services;
 - methods, processes, and equipment;
 - the release of products and services;

Traceability for Raw Material is required and shall be retained and provided to TFI with product.

- C. <u>EMPLOYEE COMPETENCE</u>: Supplier will ensure that employees and people working on its behalf are competent and trained including any additional employee qualifications;
- D. **INTERACTIONS**: TFI reserves the right to identify the requirements for interaction with our Suppliers including:
 - The use of interactive documentation
 - The use of email/Fax
 - Documented confirmation methods of all verbal interactions
 - Scheduled face-to-face meetings when required by TFI or its customers

No third party request for information will be authorized unless approved, in writing, by TFI;

- E. <u>CONTROL & MONITORING</u>: Supplier's performance will be monitored by TFI which includes:
 - On-Time Performance
 - Quality (ie. meeting requirements) of delivered products and services
 - Accuracy of Supplied Documentation
 - Completion of Documentation Requirements (identified on P.O.)

TFI will score Suppliers based on Quality, Delivery, and/or Service. Suppliers will be issued corrective actions as warranted. Any outcomes will be documented in Management Review Meeting Minutes. Suppliers that fail to perform in these areas may receive further Corrective Actions and may be considered for probation or removal from TFI's Approved Supplier List;

- F. **VERIFICATION AT PREMISES**: TFI and its customers reserve the right to perform verification and/or validation activities at the Supplier's premises.
- G. **DESIGN / PROCESS CONTROL**: TFI reserves the right to require the Supplier or sub-tier Supplier to implement and maintain design, development and process control;
- H. **SPECIAL REQUIREMENTS**: Supplier and sub-tier Suppliers are responsible for meeting special requirements, critical items or key characteristics identified;



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- I. <u>VALIDATION / VERIFICATION</u>: Supplier will maintain a quality/inspection system that will ensure all goods and services conform to contract requirements whether manufactured or processed by Supplier or procured from sub-tier Suppliers and that fully complies with requirements for test, inspection, and verification (including production process verification). For calibration Purchase Orders, all gauges and instruments must be calibrated using traceable standards (e.g. National Institute of Standards and Technology or the General Conference of Weights and Measures). All provided calibration certifications must specifically state this traceability;
- J. **PRODUCT ACCEPTANCE**: The Supplier is required to have a statistically valid sampling plan for product acceptance, unless otherwise specified by TFI;
- K. **<u>QUALITY CONTROL</u>**: TFI requires external providers to satisfy the following needs:
 - TFI reserves the right to require the Supplier or sub-tier Supplier to implement and maintain a quality management system;
 - Supplier will use customer-designated or approved sources, including process sources (e.g. special processes) when required by TFI or its customers;
 - Supplier must notify TFI immediately upon discovery any product, process or service that is nonconforming to any engineering drawing, and/or Purchase Order requirement and obtain approval for its disposition. Suppliers that receive notification of Nonconforming product shall take appropriate action to contain the nonconforming condition and prevent it from occurring again. The Supplier will be notified if formal Corrective Action is required to be submitted to TFI.
 - To prevent the use of counterfeit parts (ie. any chemical/material, part or component that is an unauthorized copy, imitation, modification or substitute that has been represented as a genuine part of an original or authorized manufacturer) Supplier will institute controls that include the requirement of Material Certificates, Certificates of Conformity, testing and/or other supporting documentation as is appropriate. Material and part substitutions are not allowed.
 - Supplier will notify TFI of any change in ownership, management, or location and are subject to re-survey and approval.
 - Supplier will notify TFI of any product or process changes or changes in approval status that affect TFI's product and are subject to re-survey and approval.
 - Suppliers shall flow-down to sub-tier Suppliers the applicable requirements as required by the purchase order including TFI and TFI's customer requirements;
 - When requested by TFI or its customers, Supplier will provide test specimens provide test specimens for design approval, inspection/verification, investigation, or auditing;
 - Supplier is required to retain all documents and records for at least 7 years, unless otherwise indicated;
 - Supplier is required to establish and maintain a Foreign Object Debris (FOD) prevention program that employs appropriate housekeeping practices to assure timely detection and removal of residue/debris generated, during operations and normal daily tasks;
- L. <u>**RIGHT OF ACCESS**</u>: TFI, its customers and regulatory authorities reserve the right to perform an onsite inspection or visit the Supplier's facility, at any level of the supply chain. TFI will give reasonable notification to the Supplier prior to the on-site inspection. The on-site inspection may include surveillance of the Supplier's facilities, procedures, production methods, processes, and the Supplier's Quality System. The Supplier shall furnish, at no cost, the necessary data as required by applicable drawings, Purchase Order, specifications, and inspection instructions to facilitate the on-site inspection;
- M. **EMPLOYEE AWARENESS REQUIREMENTS**: Supplier will ensure that employees and people working on its behalf are aware of:
 - their contribution to product or service conformity:
 - their contribution to product safety;
 - the importance of ethical behavior.