



Supply Quality Requirements

Quality Management System

Supplier shall maintain a Quality Management System (QMS) that meets the requirements of ISO 9001 or ISO 13485 (third-party registration preferred) including that personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills, and experience. Hobson & Motzer (H&M) reserves the right to require, for Suppliers without formal registration a Supplier Self-Assessment to ISO 9001 (form 4.660.03), and/or (QMS) audit at the Suppliers facility for the final determination of compliance to requirements.

Supplier Audits

For the purpose of Supplier Qualification or to identify root cause/corrective action necessary to address performance issues, Supplier shall permit H&M to conduct a Supplier Audit of its operations, personnel, and documentation. H&M shall submit notification and audit agenda to Supplier in advance of the audit. H&M shall provide an audit report and formally request Corrective Action if required, based upon the audit findings. Supplier shall respond within two weeks with a Corrective Action Plan to address the findings and timeline for completion.

Right of Entry

Representatives of H&M, its customers, and/or regulatory agencies reserve the right to visit the Supplier, and their sub-tier Suppliers with the intent of performing verification activities including but not limited to inspections, system audits, and resolution of product quality issues.

Notification of Change

The Supplier **Shall Not Implement** any changes to drawings, specifications, materials, and/or processes without written approval from H&M.

Corrective Action

When formally requested, the Supplier shall investigate non-conformities to determine the root cause of failure, and take effective action(s) as appropriate to correct and prevent future failures.

Resubmission of Rejected Material

Items returned to the Supplier by H&M that can be reworked to spec and then resubmitted by the Supplier, shall include indication of resubmission on the accompanying paperwork and shipping documents. Reference shall be made to the H&M rejection documentation and evidence presented to demonstrate that the causes for rejection have been corrected.

Submission of Non-Conforming Material

Items non-conforming with the requirements of the Purchase Order (PO), drawings, specifications, which cannot be corrected through continuation of the original manufacturing process or by rework; **Shall Not Be Submitted** without prior written approval from H&M. Submittals shall include Supplier-recommended disposition(s) with sufficient technical, quality, and reliability justification.



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Sub-Tier Flow Down of Requirements

The Supplier shall flow down all PO, drawings, and specification requirements to all sub-tier Suppliers.

Traceability

The Supplier shall maintain traceability to the raw material level, and shall be able to provide such traceability when requested by H&M.

Record Retention

The Supplier, and their sub-tier Suppliers shall maintain records to substantiate product compliance to the PO requirements and must be capable of furnishing copies of these records upon request. Such records shall be maintained for a minimum of 15 years after date of delivery to H&M.

Certificate of Conformance

“Certificate of Conformance” (C of C) shall be provided with each shipment. The C of C shall be in the Supplier’s format and may either be a separate document or included within the packing list. The C of C shall state that the items were produced in conformance with requirements as specified in the PO.

At a minimum, the C of C shall include:

- 1) Manufacturer/Distributor’s name and address
- 2) PO number referenced.
- 3) Part number and revision (when applicable)
- 4) Traceability information to include work order, material properties, lot number, heat number, date codes, serial numbers (when applicable)
- 5) Signature of the Supplier’s authorized representative

Preservation & Packaging

Unless otherwise specified, the Supplier shall use best commercial practices for preservation and packaging for all items supplied.