

CTM

Company Work Instruction

SUBJECT: Quality Clauses (Q Clauses)

WI 4.2-037

1.0 PURPOSE

The purpose of this work instruction is to control the content of the CTM Quality clauses.

2.0 PROCEDURE

Only the clauses spelled out on the face of the Purchase Order apply. If the supplier cannot meet any applicable term(s), the supplier shall notify the responsible CTM Buyer immediately. Any exception to any of the Purchase Order clauses must be approved, in writing, and signed by the responsible Buyer and/or Quality Manager.

Q1 CTM Right of Access: CTM and CTM's Customer and/or Regulatory reserves the right to inspect with notice any or all materials included in this order at the vendor's plant.

Q2 CTM Source Inspection: CTM Inspection is required at seller's facility. Evidence of such Inspection will be indicated on the shipping report, process certification, or fabrication order accompanying each shipment. Seller will notify CTM Quality Assurance Department at least Five days prior to processing or manufacturing so that appropriate planning for CTM Source Inspection can be accomplished.

Note: Seller shall provide a copy of the purchase contract to the Buyer's Quality Representative serving their plant upon request.

Q3 CTM Work Surveillance: Work under this Purchase Order is subject to CTM's surveillance at Vendor's location. CTM's Quality Assurance Representative may elect to conduct Inspection on a surveillance basis, or perform 100% Inspection. Vendor will be notified by CTM if Inspection or surveillance is to be performed on specific shipments. No shipments are to be held for CTM Inspection unless notification, in writing, is received prior to the scheduled ship date.

Q4 Government Source Inspection: Government Inspection is required prior to shipment from vendor's plant. Upon receipt of this order, promptly notify the Government Representative who normally services your plant, so that appropriate planning for Government Inspection may be accomplished. The vendor shall furnish the Government / Representative with all drawings and specifications necessary for Inspection. In the event the Government Representative cannot be located, the CTM Buyer shall be notified immediately. NOTE: Government Source Inspection does not relieve the vendor of the responsibility for the product meeting all applicable Drawing/ Specification requirements.

Note: Seller will provide evidence Of Government Inspection on their shipping report accompanying each shipment.

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- Q5 CTM Customer and Regulatory Inspection: During performance on this contract, your quality control or Inspection system, manufacturing process, and records are subject to review, verification, & analysis by authorized representative. Source Inspection or release of product prior to shipment is not required, unless notification, in writing, is received prior to the scheduled ship date.
- Q6 CTM's Customer Source Inspection: CTM Customer Source Inspection is required prior to shipment from vendor's plant. Upon receipt of this order, promptly notify CTM Quality Assurance department so that appropriate planning for CTM Customer Source Inspection may be accomplished. The vendor shall furnish the Representative with all drawings and specifications necessary for Inspection.

Note: Seller will provide evidence of CTM's Customer Source inspection on their shipping report accompanying shipment.

- Q7 First Article Inspection: CTM Quality reserves the right to perform a Source First Article Inspection. The vendor shall notify the Buyer 72 hours in advance that the article/item is ready for Inspection. Evidence of such Inspection will be indicated on the shipping report, process certification, or an Inspection document accompanying each shipment in accordance with AS9102.
- Q8 General Compliance: By the acceptance of this Purchase Order, Seller agrees that materials/items and/or finished parts shall be controlled, Inspected and tested in compliance with, and will meet all specified Purchase Order requirements drawing/ specifications, and that applicable records are on file for at least **ten (10)** years, subject to CTM or CTM's Customer examination. **Any record that is not sent to CTM per the these quality clauses will be required to be retained by the Seller/ Supplier. They will need to be identifiable to CTM's P.O., legible, stored properly, protected and retrievable for a period of 10 years.**
- Q9 Specific Compliance: The vendor shall furnish a Certificate of Compliance (C of C), signed by an official representative for the vendor. Materials, Processes, Services and/or furnished items, in accordance with the instructions, drawings/specifications furnished with the Purchase Order shall have signed Certification included with the Packing Slip in the form of a C of C. Each C of C shall identify the Purchase Order Number, Part Number, revision, Serial Number, if applicable, Specification, Drawing, and lot/batch number as applicable to the content of the Purchase Order. Inspection and Test data shall be maintained for **ten (10)** years, unless otherwise specified, and is subject to CTM or CTM's Customer examination. The C of C must state the name of the manufacturer when ordered from a distributor, and shall accompany each shipment.

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Q10 Inspection/Test Data: One (1) copy of actual Inspection/Test Data shall accompany each shipment.

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- Q11 Corrective Action: Seller shall, on request, on forms designated by Buyer, provide statements of Corrective Action on failures of seller's hardware. Corrective Action statements, at buyer option, may require approval signature by Buyer Quality & Government Quality representatives. All rejected articles resubmitted by seller to Buyer shall bear adequate identification including reference to Buyer's rejection document.
- Q12 Dimensional Data: The vendor shall submit Recorded Dimensional findings with each shipment. Vendors Inspection Equipment shall be Calibrated and traceable to the NIST.
- Q13 Workmanship: All items on this order shall be fabricated, processed, protected and finished in such a manner as to be uniform in quality and appearance and be free of defects that will affect form, fit, function, life, safety or serviceability.
- Q14 Manufacturing & Inspection Control Plan: Seller will submit a manufacturing & Inspection control plan for CTM approval. As a minimum, the plan will delineate the sequence of manufacturing operations to be performed, the type of each Inspection specified, &, if applicable, the specifications that define each Inspection requirement. This plan will be submitted to CTM's purchase order originator & approved by CTM Quality Assurance prior to production of the product ordered. CTM's approval of this plan does not relieve Seller of the responsibility to perform all Inspection required by the applicable specifications. After approval by CTM's Quality Assurance seller will comply with the plan submitted. Any changes to the approved plan will be submitted to CTM for re-approval.
- Q15 First Piece Inspection: The vendor shall submit a First Piece sample item for dimensional and/or functional approval prior to producing production items. The vendor shall notify CTM Buyer when the item is ready for approval examination. CTM may choose to perform examination at vendor's facility or may require vendor to ship sample part(s) to CTM for examination. Notification of place of examination, in either case, will be made in writing by CTM.
- Q16 Traceability/Records: The vendor shall retain records as a means of objective evidence of the quality of items supplied (manufactured, fabricated, assembly, Inspection, Test, Special Processes, etc..) for a minimum of **ten (10)** years, or as otherwise indicated on the Purchase Order. All records shall be maintained in a manner to prevent deterioration. Records shall be subject to examination by CTM or CTM's Customer copies of these records shall also be available upon request. Once the required retention time has passed all records shall be shredded and disposed of.
- Q17 Age Control: The vendor shall include the material type, condition, lot or batch number, specifications, Manufacturer, date of Manufacture, and shelf life expiration date, on all perishable/shelf life material Certifications. The vendor shall supply the Hazardous Material Identification

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System (HMIS), the Manufacturing Data Sheets, when applicable, and the Material Safety Data Sheets (MSDS) with the material, as required.

- Q18 Dealers and Distributors: The vendor must supply Manufacturers Certification with each shipment.
- Q19 Material Test Reports: The vendor shall submit a copy of the Chemical and Physical Test Report with actual Test Data for the materials shipped under this order. Seller will mark each individual item and applicable document, test report, shipping report, & certification to show clear traceability to lot, heat lot, or batch number. Unless otherwise directed by purchase order or the specification, when the size of the item does not permit marking of individual items, Seller will label each package or box furnished.
- Q20 Retained Data: Physical and Chemical Test Data of raw materials used in the fabrication of articles on this order shall be retained on file by the supplier for a period of **ten (10)** years, and are subject to CTM or CTM's Customer examination, and a copy furnished upon request.
- Q21 X-Ray Inspection: When X-Ray Inspection is required, the X-Ray number shall be marked on the material when so required by specifications. X-Ray photographs identifying part and position shall be maintained by the vendor, and submitted to CTM upon request. An X-Ray Inspection report shall be submitted with each shipment.
- Q22 Lot Control: Lot identification number(s) shall be supplied with material/items, Inspection Records/ Data traceable to the lot number identification, shall be available upon CTM request.
- Q23 Statistical Process Control (SPC): SPC requirements including SPC Data are required on this order.
- Q24 Configuration Control: The vendor shall supply the revision(s) specified on this Purchase Order, unless a change is authorized, in writing, by CTM Buyer prior to shipment.
No changes or substitutions can be made to components, products, services or the processing of those components, products or services without prior written notification and approval of CTM. This includes but is not limited to the location of manufacture.
- Q25 Casting Information: All Castings on this order shall be identified by a permanent casting number, part number and configuration, or by a method that will give complete trace ability of mold used in fabrication. Physical and Chemical Test Data of raw materials furnished on castings produced on this order shall denote the applicable heat number, batch or lot number, date of manufacturer, and shall be furnished with each shipment.
- Q26 Packaging: Packaging materials shall not have a harmful effect on items shipped on this order. Packaging, unless otherwise specified, shall be performed to completely protect items from damage

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or deterioration during shipment.

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- Q27 Sub-Contracting of this Purchase Order: Sub-Contracting of this Purchase Order other than original release to, is prohibited without prior written authorization from CTM's purchasing Buyer and CTM's Quality Assurance Department.
- Q28 Process Control: The vendor shall maintain control and approval of all Manufacturing (i.e.. welding, soldering, plating, painting, etc..) and Inspection/Test, used in the performance of this order. The vendor shall maintain objective evidence of process qualification in accordance with applicable specifications. The approval status shall be subject to review and approval/disapproval by CTM or CTM's Customer.
- Q29 Over/Under Shipments: No Over/Under shipments are allowed on this order without prior written authorization from CTM's purchasing department.
- Q30 Calibration Control: The vendor shall control the Calibration of all Measuring and Test Equipment (M &TE) against Certified Measurement Standards, traceable to the NIST. The Calibration Control System shall conform to specification ISO 10012, ISO 17025, or equivalent.
- Q31 Sellers Compliance With ISO 9001: Seller will comply with ISO 9001, Inspection System Requirements or equivalent. Seller is required to be on CTM approved supplier listing.
- Q32 Notification of Non-Conforming Product: Seller shall notify CTM immediately after discovering non-conforming product. At this time CTM will determine the disposition of the product, if the disposition is use-as-is the non-conforming material should be tagged and inspection data describing the non-conformance should accompany the product.
- Q33 Customer Approved Sources: Seller is required to use Customer Approved Special Process Sources. The purchase order issued by CTM, Inc. will be accompanied by a list of Customer Approved Special Process Sources. The processes, which require the use of these sources, will be identified on the purchase order.
- Q34 Counterfeit Parts: The supplier has the responsibility to verify that unauthorized copy, imitation, substitute, or modified part (e.g., material, part), is not knowingly misrepresented as a specified genuine part of an original or authorized manufacturer of such part.
- Q35 Supplier Awareness: The supplier is responsible is an integral part of our QMS with product conformity, must ensure product safety and adhere to ethical behavior.

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3.0 REVISION HISTORY

Approved by _____ Date _____

Revision	Date	Revised By	Description of Change	T r a i n i n g Required
NEW	08/01/05	S. Pileggi		NO
_1	07/07/06	Russ V.	See DCR 056	NO
_2	06/18/07	Russ V.	See DCR 065	NO
_3	06/04/12	B. Nestle	See DCR 117	NO
_4	03/20/18	B. Nestle	Added 34 and 35	NO
_5	10/06/2021	Gregg P.	Added Change Control Requirement to Q24(Ref. Getinge SCAR 21-M-SCAR-262)	Y