

Standard Operating Procedure

Procurement, Materials

SOP #: 3.004 Rev. 4

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Approval

Approving Authority	Name	Signature	Date
President	Joseph Parisi	M	12/23/13
Operations Manager	Steve Hansen	8	12/23/13
V.P. Engineering	Steve Rusconi	SR	12/23/13
Process Systems Manager	Michael Delgado	MOD	12/26/13
Quality Assurance Manager	Steve Washington	to T. Way L	12/26/13

Revision History

Revision #	Description of Change	Effective Date	DCR#
3	Data modifications	05/07/97	97027
4	Add Revision History, Revise Header, and Data modifications	12/26/2013	13001
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Purpose

1.1 To establish a standard procedure for ordering materials.

2 Scope

- 2.1 This procedure applies to the purchasing of materials, equipment, and instrumentation for piping or pressure vessels to be built to ASME codes of construction B31.1, B31.3, Bioprocessing Equipment (BPE), Boiler and Pressure Vessel Code (BPVC) or National Board Inspection Code(NBIC).
- 2.2 The procedures apply to the use of the database purchasing system, Therma's True-Trac.

3 References

- 3.1 ASME code for pressure piping, B31.1 Power Piping
- 3.2 ASME code for pressure piping, B31.3 Process Piping
- 3.3 ASME Bioprocessing Equipment (BPE)
- 3.4 ASME Boiler and Pressure Vessel Code (BPVC)
- 3.5 National Board Inspection Code (NBIC)
- 3.6 Therma ASME Quality Control Manual

4 Responsibility

- 4.1 The Therma Project Manager (PM) shall ensure this procedure is followed and may designate a Purchasing Agent (PA) at the beginning of the project.
- 4.2 PM or PA will perform the following procedures.
- 4.3 The Therma Quality Control Manager shall review all Purchase Orders(PO) for projects built to ASME BPVC or NBIC prior to issue to the vendor per Therma's ASME Quality Control Manual.

5 Procedures

5.1 Specification Review



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- 5.1.1 Obtain a copy of an approved submittal.
- 5.1.2 Obtain a copy of the specifications.
- 5.1.3 PM to complete SOP Form FN 7.002.2 Specification Acceptance Criteria per Therma SOP #7.002 Quality Control Examination Pharmaceutical Material as required for validated High Purity and BPE projects.
- 5.1.4 PM shall transmit completed form to the Quality Control Manager for later reference when performing material examinations.

5.2 Material List

- 5.2.1 PM or Foreman shall create material list for items to be purchased. At a minimum, the material list shall contain the following information:
 - 5.2.1.1 Job name and number
 - 5.2.1.2 Requester's name
 - 5.2.1.3 Item description
 - 5.2.1.4 The applicable (piping) system(s)

5.3 Purchasing

- 5.3.1 PA or PM shall review the material list(s) for completeness and compliance with submittals and specifications.
- 5.3.2 PA or PM shall price out the materials.
- 5.3.3 Complete a Purchase Order (PO) form.
- 5.3.4 Complete the description of materials and unit prices using the negotiated/quoted pricing. When possible, give common language description as well as manufacturer's part number.
- 5.3.5 Note any extra processing steps required for each line item prior to QC acceptance.



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- 5.3.5.1 For example: if materials, as they are received, require electro-polishing prior to QC acceptance, then this shall be noted on the Purchase Order.
- 5.3.6 When ASME Bioprocessing Equipment (BPE) code applies for process contact materials, each item shall note
 - 5.3.6.1 "ASME BPE", current edition
 - 5.3.6.2 Surface finish designator (SF#)
 - 5.3.6.3 Dimension and tolerances "DT" table number
 - 5.3.6.4 Outside diameter/size and configuration
 - 5.3.6.5 Wall thickness
 - 5.3.6.6 Alloy/material type
 - 5.3.6.7 Pressure ratings for valves
 - 5.3.6.8 Material test reports (MTR) and/or certificate of compliance (COC) required with all deliveries.
 - 5.3.6.9 Special processing required upon receipt and prior to release for fabrication (For example: mechanical polishing to 15 Ra, then electro polishing required.)
 - 5.3.6.10 General Note: Refer to Diagram B (SAMPLE Purchase Order) for reference.
- 5.3.7 Indicate on the PO the Therma employee to whose attention the delivery should be made.
- 5.3.8 Note the delivery location required and estimated delivery dates. If some items will be longer lead times, insert the expected delivery date on the line item.
- 5.3.9 If the item being purchased requires Material Test Reports, Certificates of Analysis, Certificates of Authenticity, etc., these documentation requirments shall be noted on the PO.
- 5.3.10 PA or PM shall review the PO for completeness and compliance with submittals and specifications.
 - 5.3.10.1 For ASME BPVC and NBIC projects, the QCM shall review and sign all Purchase Orders prior to issue per Therma's ASME QC Manual.
- 5.3.11 Print the PO Sign and date.
- 5.3.12 Print the Packing Slip Verification (PSV) form.

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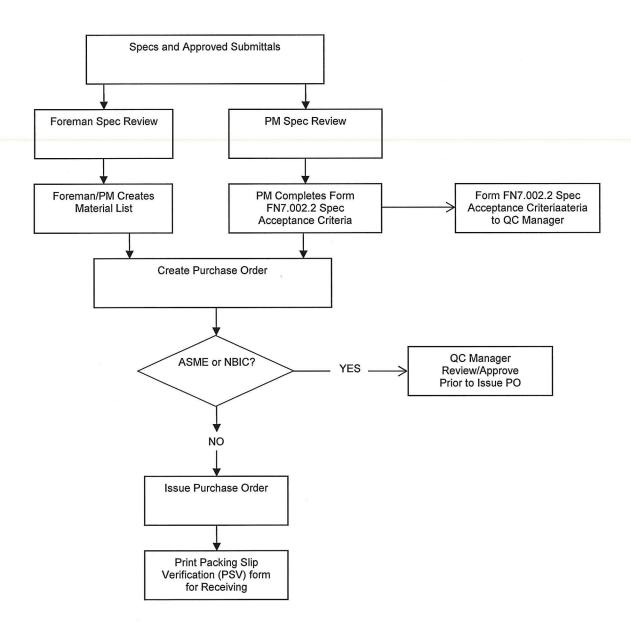
- 5.3.13 Gather the applicable paper work to be attached to the PO.
 - 5.3.13.1 Terms and conditions
 - 5.3.13.2 Vendor quotation
 - 5.3.13.3 Subcontractor/vendor agreement
 - 5.3.13.4 Special requirements to the PO.
- 5.3.14 Fax or email the package to the vendor.
- Note: If multiple orders are being placed with one vendor for the same piping specification, the approved submittal data, specifications, and vendor agreement need only to be included in the first order only. Subsequent PO's must reference the attached approved submittal data and specifications from the first PO.
- 5.3.15 PO filing PM or PA shall insert into PO File.
- 5.3.16 PSV filing PM or PA shall deliver the Packing Slip Verification (PSV) Form to receiving.
 - 5.3.16.1 Attach vendor quotation to PSV if data is required to properly reveive the materials.
- 5.3.17 Purchase Orders in the Therma's True-Trac database purchasing system are logged automatically by the software which can generate a PO Report as needed.
- 5.4 Diagrams
 - 5.4.1 Refer to Diagram A:Purchasing Document Flow Chart
 - 5.4.2 Refer to Diagram B:Sample Purchase Order with notes.



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DIAGRAM A: DOCUMENT FLOW CHART



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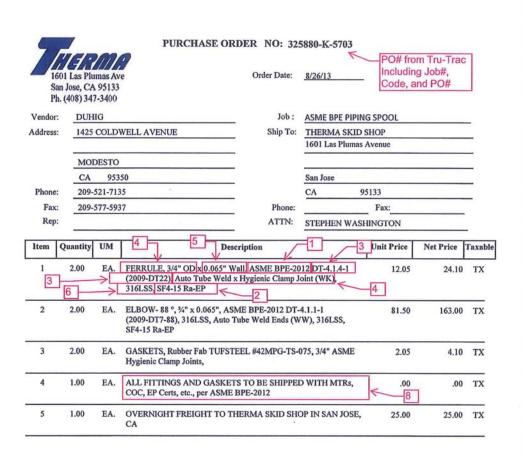
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DIAGRAM B: SAMPLE PURCHASE ORDER



The Purchase Order number above must accompany all invoices in order for payment to be processed. By undertaking performance of this Purchase Order, vendor acknowledges the terms of agreement (attached) and further acknowledges that said terms are specifically incorporated by this reference.

All documents, including invoices, must be sent to Therma San Jose Office at 1601 Las Plumas Avenue, San Jose, California, 95133-1613

- 1. ASME Bioprocessing Equipment (BPE) Standard, Current Edition
- 2. ASME BPE Surface Finish Designation
- 3. ASME BPE Dimensions and Tolerances Table Number (DT-##)
- 4. Outside Diameter/Size and Configuration
- 5. Wall Thickness
- 6. Alloy/Material Type
- 7. Pressure Ratings for Valves (not shown)
- 8. Material Test Reports(MTR), Certificate of Conformance(COC)

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