



Standard Operating Procedure

SOP #: 7.002 Rev. 9

Quality Control Examination of Pharmaceutical Material

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Approval

Approving Authority	Name	Signature	Date
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Quality Assurance Manager	Steve Washington		3/24/14

Revision History

Revision #	Description of Change	Effective Date	DCR#
4	-	-	99060
5	-	03/30/06	06004
6	Add Borescoping frequency	05/04/07	07008
7	Change Inspect to Examine, QC Inspector to QC Examiner	02/17/12	10018
8	Add Rev. History, Rev. Header, and Add Equip./Instr./Valves & Random PMI Testing	11/19/13	13009
9	Add Ref. to 5.001 and Sulfur Content Limits per BPE, Edits to PMI Testing	03/28/14	14001

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1 Purpose

- 1.1 To establish a Quality Control Standard Operating Procedure(SOP) for the examination of materials utilized in fabrication of piping or piping systems for the Bioprocessing industry.

2 Scope

- 2.1 This procedure applies to all incoming equipment, instruments, valves, piping, fittings, and other process or product contacting materials requiring a quality control examination before use.
- 2.2 All process/product-contacting material shall meet the project specifications as outlined in Form FN 7.002.2 Specification Acceptance Criteria.
 - 2.2.1 For projects without applicable customer specifications, all process/product -contacting materials shall conform to acceptance criteria noted in current American Society of Mechanical Engineers' (ASME) Bioprocessing Equipment (BPE) standard.

3 Responsibility

- 3.1 The Therma Quality Control Examiner (QCE) shall perform the procedures listed below.
- 3.2 The Therma General Foreman(GF) and Receiving Clerk(RC) shall coordinate with the QCE when material has been received and is ready for examination.
- 3.3 The Therma Quality Control Manager (QCM) shall coordinate with Owner's inspector or third party inspector to perform material inspections and weld inspections per project specifications.
- 3.4 The Therma Project Manager (PM) shall complete SOP Form 7.002.2 specification acceptance criteria for all projects requiring QC exams of materials.

4 Special Tools Required

- 4.1 Profilometer (surface relative roughness measuring tool)
- 4.2 Dial or Vernier calipers (6" recommended)
- 4.3 Borescope with video recorder and character generator

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- 4.4 Flashlight for ID illumination
- 4.5 Weld inspection mirror
- 5 Procedures
 - 5.1 Ensure the material is being stored in the "Quarantined Material" storage areas.
 - 5.1.1 The "Quarantined Material" storage area shall be defined by the Quality Control Manager(QCM) for each shop (SS pre-fab, Process Systems, etc.) or field work site per SOP 5.001 Receiving and Storage.
 - 5.1.2 Access to materials in these areas shall be restricted to receiving clerks to add new incoming materials and QCM/QCE to perform QC examinations.
 - 5.1.3 No material shall be removed from "Quarantined Material" area for use in production until QCM or QCE performs required examinations per project specifications, accepts and releases the materials for fabrication per the following procedures.
 - 5.2 Obtain copies of Packing Slip Verification (PSV) form, Packing Slip (PS), Material Test Reports (MTR) and associated data sheets, submittal info, vendor quote, etc., as required to verify compliance with project specifications.
 - 5.3 Obtain copy of project specifications and form FN 7.002.2 Specification Acceptance Criteria from the Project Manager and review it for the material to be examined for that particular job.
 - 5.4 Perform a visual examination and verify that the materials have not been damaged in freight.
 - 5.5 Ensure that the material meets the acceptance criteria for Dimensions and Tolerances, Material Composition and Surface Finish, etc., by examining the materials as per current ASME BPE standard:
 - 5.5.1 Equipment: Pumps, pressure vessels, heat exchangers, etc.
 - 5.5.1.1 Examine equipment to verify conformance with project specifications, Purchase Order(PO), data sheets, quotes, etc., especially dimensions, connection types, materials, surface finish, etc.

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5.5.1.1.1 For pumps, QCE shall complete form FN 7.002.6 Pump Examination Report.

5.5.1.1.2 For heat exchangers, QCE shall complete form FN 7.002.7 Heat Exchanger Examination Report.

5.5.1.1.3 For pressure vessels, QCE shall complete form FN 7.002.9 Pressure Vessel Examination Report.

5.5.1.1.4 For other equipment items, QCE shall complete form FN 7.002.10 Equipment Examination Report.

5.5.1.1.5 Weld Ends that are to be autogenously welded shall have sulfur content between 0.005% and 0.017% by weight per current ASME BPE.

5.5.2 Instruments: Flow, pressure, temperature, wet/dry and analytical (pH, conductivity) sensors.

5.5.2.1 Examine instruments to verify conformance with project specifications, Purchase Order(PO), data sheets, quotes, etc., especially dimensions, connection types, materials, surface finish, etc.

5.5.2.1.1 For instruments, QCE shall complete form FN 7.002.8 Instrument Examination Report.

5.5.2.1.2 Weld Ends that are to be autogenously welded shall have sulfur content between 0.005% and 0.017% by weight per current ASME BPE.

5.5.3 Valves: Sanitary diaphragm/weir ball, globe, control and other valves.

5.5.3.1 Examine valves to verify conformance with project specifications, Purchase Order(PO), data sheets, quotes, etc., especially dimensions, connection types, materials, surface finish, etc.

5.5.3.1.1 For valves, QCE shall complete form FN 7.002.5 Valve Examination Report.



5.5.3.1.2 Weld Ends that are to be autogenously welded shall have sulfur content between 0.005% and 0.017% by weight per current ASME BPE.

5.5.4 Piping: Tube, fittings, clamps, gaskets, etc.

5.5.4.1 Examine pipe, tube, fittings, etc. to verify conformance to project specs, Purchase Order(PO), data sheets, quotes, etc., especially dimensions, connection types, materials, surface finish, etc.

5.5.4.1.1 Ovality (i.e. Tube's permissible variations in outside diameter) – See ASME BPE (typical).

5.5.4.1.2 Surface Finish (internal surface only)

5.5.4.1.3 Wall Thickness

5.5.4.1.4 Borescope the material as per SOP 7.006 (Borescoping)

5.5.4.1.5 Weld Ends that are to be autogenously welded shall have sulfur content between 0.005% and 0.017% by weight per current ASME BPE.

Note: On a given tube if there is a defect that can be cut out in order to use the remaining tubing, mark on the exterior of the tube the location of the defect. Hold tubing until the prefab foreman demonstrates that the anomaly has been cut out. Then label the remaining tubing "Accepted for Use."

5.6 Record the examination results, purchase order number and material/mill test reports (MTRs) on Form FN 7.002.1 Material Examination Log.

5.7 Perform random Positive Material Identification(PMI) testing following SOP 7.033 Operation, Calibration and Maintenance of Alloy Analyzer.

5.7.1 A minimum of one randomly selected sample shall be selected for each applicable job for PMI testing.

5.7.2 When possible, the random sample shall be selected from different vendors/manufacturers.

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- 5.7.3 The vendor shall be selected by the QCM and Project Manager(PM) during the 'kick-off' phase of the project. The QCM shall maintain a suitable log for recording the following data: Date, Job#, Manufacturer, Heat #, Specified Alloy and Material as Tested.
- 5.8 Upon completion of material examination, QCE/QCM shall:
- 5.8.1 Designate the materials as either "Accepted" or "Rejected".
- 5.8.2 Cap off all openings of the material with appropriate plastic end protection ("Caplug" manufactured by Protective Industries, Inc. or equivalent).
- 5.8.3 Identify the Accepted material with markings: Accepted - job#.
- 5.8.4 If Accepted materials include tagged items such as equipment, instruments and valves; QCM/QCE shall verify attachment of SS identification tag matching the P&ID per customer's specifications as required.
- 5.8.5 Accepted Material Test Reports shall be stamped "APPROVED THERMA CORP.", initialed and dated by the QCM or QCE.
- 5.9 If the material passes the examination, move it to "Accepted the Material" area for project.
- 5.9.1 The "Accepted Material" storage area shall be defined and labeled for each applicable project.
- 5.9.2 Refer to SOP 5.001 Receiving and Storage for further instructions.
- 5.10 If the material is rejected for use, QCE will cap off all openings of rejected material and place the material in the "Rejected Material" area.
- 5.10.1 The "Rejected Material" storage area shall be defined by QCM for each shop or field work site.
- 5.10.1.1 Access to "Rejected Materials" area shall be restricted to QCM and QCE only.
- 5.10.2 Record details for the rejected material on SOP Form FN7.002.4 Rejected Items Log, including: Description, Quantity Ordered, Date



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Received, Vendor, Date of Exam, Quantity Accepted, Quantity Rejected and comments.

- 5.11 QCE will notify the prefab foreman of the results.
- 5.12 QCE will make a copy of the SOP Form FN7.002.1 Material Examination Log (MEL) and attach with MTR(s), PSV, PS and other documents per SOP 5.001 Receiving and Storage. File the copies in the job binder.

6 Review and Approval

- 6.1 Revisions to this document requires review and approval by the Quality Management team prior to inclusion into the Therma Quality SOP system.

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