

Standard Operating Procedures For IAPMO Evaluation Service (IAPMO ES)

No.: ES-010

Title: Minimum Requirements for Listee's Quality Assurance System

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Ck:AZ

Approved By: SM

Rev Date:6/16/08

1.0 Scope: The quality system shall be composed of written procedures, which are to be followed at the Supplier's applicable site(s).

2.0 Responsibility: The Senior Director of Evaluation service and the Director of Continuous Compliance are responsible for ensuring that the quality system as written is reviewed during audits.

3.0 Product Identification: The manufacturer shall establish and follow written procedures for identifying the product during all stages of production.

- 3.1 The manufacturer shall ensure that incoming raw materials and components are inspected or tested to verify conformance to requirements specified in appropriate product standards. Certification by approved vendors is permitted.
- 3.1.1 If approved vendors certifications are used to establish conformance of materials, the QC manual shall contain written procedures for approval of vendors.
- 3.1.2 If approved vendors certifications are used to establish conformance of materials, the QC manual shall contain written procedures for independent verification of those properties that impact the design assumptions used to engineer the products.
- 3.2 When incoming raw materials and components are released without inspection for urgent production purposes, the finished products and the raw materials and components shall be positively identified and recorded in order to permit recall and replacement in the event of non-conformance to specified requirements.
- 3.3 The manufacturer shall establish and follow written procedures for inspecting and/or testing finished products.
- 3.4 The manufacturer shall identify nonconforming products
- 3.5 Frequency of sampling and testing shall be established.
- 3.6 The procedures for inspection and testing shall require that all specified inspections and test have been carried out and documented and that the product meets specified requirements before product may be released for shipment bearing an IAPMO ES mark of conformity.
- 3.7 Test Records: The manufacturer shall maintain records which give evidence that the product has passed all phases of inspection and/or testing and has been found to be in compliance with manufacturer's defined acceptance criteria.

4.0 Inspection, Measuring and Test Equipment: The manufacturer shall control, calibrate and maintain all inspection, measuring and test equipment used in the inspection and testing program, to demonstrate conformance of products to the specified requirements.

- 4.1 Identify, calibrate, adjust and maintain calibration records for all inspection, measuring and test equipment and devices that can affect product quality prior to use or at prescribed intervals. The foregoing shall be accomplished utilizing certified equipment having a known valid relationship to nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented.
- 4.2 Establish, document and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory.

5.0 Inspection and Test Status: The inspection and test status of the product shall be identified by using markings, authorized stamps, tags, labels, physical segregation or other suitable means which indicate the conformance and nonconformance of product with regard to inspection' and test performed.

- 5.1 Documents shall identify the inspection authority responsible for the release of conforming products

6.0 Control of nonconforming products: Supplier shall establish and implement procedures to ensure that the products identified in section 4.0 that do not conform to specified requirements are prevented from inadvertent shipment.

- 6.1 Nonconforming products may be reworked to meet the specified requirements; accepted with or without repair by concession; re-graded for alternative applications; or scrapped.

7.0 Administrative: The Quality Assurance documentation shall include the following:

- 7.1 Organizational charts, resumes indicating qualifications of key personnel and their responsibility relative to the quality control function.
- 7.2 A quality policy statement including objectives and commitments
- 7.3 Signature of the responsible party.

8.0 Complaint Record: Manufacturer shall establish and follow written procedures for complaints received from customers, and keep records of all complaints.



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Pre Audit Checklist

Listee: _____ Report Date: _____
 Mfr.(if different): _____ Plant Contact: _____
 Mfr. Address: _____
 City: _____ State: _____ Zip: _____ Country: _____
 Phone: _____ Fax: _____ Email: _____

v-Quality Assurance Manual Review,

Is there a revision date on the QA manual,

IS there an org chart in the QA manual

Is it signed by the person responsible for its implementation

are current versions of standards on site? List them

OK	NG

1.0 not used

2.0 not used

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Section	OK	NG

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vi-Items to review:

	OK	NG
Review of raw material inspection and acceptance Records		
Review of defective material quarantine		
Review testing records		
Review of the testing equipment calibration records		
Review of customer complaint records		
Review of defective material quarantine		
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vii-Walk the production line

	OK	NG
From the beginning to the end. Receiving to shipping.		
See the testing equipment in action		
Perform a sample test we do to ensure quality.		
Where do we calibrate the measuring tools		
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