IAPMO UNIFORM EVALUATION SERVICE, LLC

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Form QR-1

INITIAL QUALITY INSPECTION REPORT

Complete all of the requested information. State the reason if the information is not available. Check N/A where not-applicable. Use additional pages when necessary to fully describe the information or inspection results.

Report, Listing or File No.: _____ Inspection Date: _____

Report Holder: _____

Product(s) Inspected: _____

Additional Company Names: _____

Masked Listee Report Nos.

Name of Manufacturer: _____

Address of Manufacturer: _____

Name & Title of Manuf. Rep: _____

Phone Number: Fax Number: E-mail:

Name of Inspection Agency: _____

Name(s) of the Inspector(s): _____

Inspector(s) E-mail:

INSTRUCTIONS

1 - Conduct an entrance interview with the manufacturer representative:

Explain the purpose of the initial inspection, which is to review the quality management system documentation and implementation. This includes reviewing procedures for incoming material verification, quality checks, personnel training and responsibility, equipment and calibration, product specifications, product and process changes, labeling and traceability, complaints, and maintenance of quality control records with the goal of verifying that the Quality Control (QC) process is functioning as described and the product being labeled is consistent with that which is recognized in the evaluation report, listing, or draft. Inquire as to the readiness of the facility to undergo the initial inspection; confirm that the facility is operating in accordance with the latest approved quality control manual (QCM) and the product meets the specifications. The product that is the subject of the evaluation report must be in production for the initial inspection to take place. If the facility is not ready, rescheduling the initial inspection should be considered.

Complete the basic information identifying the product, the manufacturing facility, and the inspection agency on this page. Obtain from IAPMO UES a copy of the latest approved QCM and current/relevant evaluation or listing report or draft for reference during the inspection. Inquire as to the product that is currently being produced, if any of the product being produced is for additional company names or masked report holders, and if there are any tests scheduled or sampling needed. Make sure to review any special instructions concerning the inspection that may have been provided by IAPMO UES.

2 - Perform the initial inspection and document the results: (See Page 2)

3 - Conduct an exit interview:

The inspector must complete the section titled "Initial Inspection Overview" to document the overall results of the inspection, record the inspector's findings in Appendices A and B, then conduct an exit interview with the Manufacturing Representative. The inspector and the representative must go over the inspection documentation, review the comments and concerns, and discuss any Corrective Action Requests (CARs) that are issued. Finally, the initial inspection report must be signed and dated by the inspector and by the manufacturing representative to acknowledge understanding of the issues. Any CARs must be addressed by the manufacturer within 30 days (see Appendix B). A re-inspection may be required depending on the circumstances.

Documenting the initial inspection:

Conduct the inspection using the following questions as a guide to areas that need to be verified. Answer these questions and provide comments as appropriate for each. If any of the findings rise to a level of significance that require follow-up, but not as an immediate condition of recognition, Appendix A is provided to record these Comments/Concerns. If any of the findings rise to the level where corrective action must be taken to allow continued recognition, Appendix B is provided to record Corrective Action Requests (CARs).

ES-010 Points of QC Verification (POV)

A. PERSONNEL

1. [POV – 3] Do the responsibilities of key personnel and the organizational chart listed in the quality documentation match the personnel and reporting structure in place in the manufacturing facility?

   (If no, attach a copy of new organizational chart and description of duties, along with an updated revision log.)

   ◯ Yes ◯ No

   Comments: _____

2. [POV – 3a] Does the quality control manual require specific training and/or certification for key operations in the production and/or quality control procedures, and do the records reflect that the relevant personnel meet these qualifications?

   ◯ Yes ◯ No

   Comments: _____

B. MANUFACTURING PROCESS

1. [POV – 7] Is the production flowchart or description of production methods, highlighting stages of significant effect on product quality, contained in the Quality Documentation representative of the actual production flow and process?

   ◯ Yes ◯ No

   Comments: _____

2. [POV – 11] Are non-conforming or non-compliant materials identified and segregated adequately and as noted in the Quality Documentation?

   ◯ Yes ◯ No

   Comments: _____

C. EQUIPMENT & CALIBRATION

1. [POV – 9] Does the manufacturer maintain up-to-date calibration records for all relevant production, measuring, and testing equipment essential to the performance of the product?

   ◯ Yes ◯ No

   Comments: _____

2. [POV – 9a] Is the measuring and testing equipment calibration current and traceable to a relevant National Standard?

Yes No

Comments:

D. QC PROCESS

1. [POV – 6a] Does the Manufacturer conduct the required test(s) and/or inspection(s) on the incoming materials as specified in the Quality Documentation and are these procedures adequate to verify conformity?

Yes No

Comments:

2. [POV – 8] Is the Manufacturer conducting the necessary In-Process Quality Control during manufacturing as described in the Quality Documentation?

Yes No

Comments:

3. [POV – 10] Does the Manufacturer conduct final testing and inspections to verify compliance before releasing the labels for application?

Yes No

Comments:

4. [POV – 14] Does the Manufacturer have adequate procedures for making changes to the QC process and reporting these changes to the inspection agency and IAPMO UES for verification of continued recognition?

Yes No

Comments:

E. DOCUMENTATION

1. [POV – 1] Are the Report Holder and Manufacturer name, contact, and location information consistent with the Quality Documentation?

Yes No

Comments:

2. [POV -10] Is the product being manufactured described adequately by the Evaluation Report, listing, or draft and in the Quality Documentation?

Yes No

Comments:

3. [POV – 4] Are the Quality Documentation and/or Quality Control Manual that are currently used during manufacturing consistent with the approved documentation provided by IAPMO UES?

   ◯ Yes ◯ No

   (If no, have Manufacturer provide updated copy of the revision log and/or quality documents.)

Comments: _____

4. [POV – 4a] Are there procedures in place to control the quality documentation to ensure the applicable editions or revisions are available and used where required?

   ◯ Yes ◯ No

Comments: _____

5. [POV – 4] Does the manufacturer perform annual quality management system audits?

   ◯ Yes ◯ No

Comments: _____

F. RECORD KEEPING

1. [POV – 12] Are the procedures followed for recording significant quality data throughout production as stated in the Quality Control Manual and are these procedures adequate?

   ◯ Yes ◯ No

Comments: _____

2. [POV – 12] Does the Manufacturer maintain records of all the data, inspections, and quality tests performed during manufacturing for a minimum of two (2) years?

   ◯ Yes ◯ No

Comments: _____

G. PRODUCT

1. [POV – 10] Does the recognized product's (products') Quality Documentation contain product description(s), specifications, standards, assembly drawings and manufacturing tolerances?

   ◯ Yes ◯ No

Comments: _____

2. [POV – 10] Do the finished product(s) meet the specifications found in the Quality Documentation?

   ◯ Yes ◯ No

Comments: _____

3. [POV – 10] Is the Manufacturer conducting the final inspection(s) or test(s) required in the Quality Documentation prior to final approval and labeling of the finished product?

   ☐ Yes ☐ No

Comments: _____

4. [POV – 14] Are there adequate procedures for making changes to the products, and reporting these changes to the inspection agency and IAPMO UES for verification of continued recognition?

   ☐ Yes ☐ No

Comments: _____

H. LABELING

1. [POV – 10a] Do the labels being used on the product match those described in the Quality Documentation and in the Evaluation Report, listing, or draft?

   ☐ Yes ☐ No

   (If not, attach a copy of the label(s) for review by IAPMO UES.)

   a) Are the label(s) for Masked Listees, if any, the same as noted in their Evaluation Report, listing, or draft?

      ☐ Yes ☐ No ☐ N/A

   b) Are the label(s) for Additional Company Names, if any, the same as noted in their Evaluation Report, listing, or draft?

      ☐ Yes ☐ No ☐ N/A

Comments: _____

2. [POV – 10a] Does the manufacturer have adequate methods to secure the labels and to prevent the labels from being misapplied or misused?

   ☐ Yes ☐ No

Comments: _____

I. COMPLAINTS

1. [POV – 13] Are there adequate procedures for identifying and recording complaints?

   ☐ Yes ☐ No

Comments: _____

J. TRACEABILITY

1. [POV – 7a] Perform a Traceability study. Does the study reveal an ability to isolate the root cause of non-conformances when and where they occur?

   ☐ Yes ☐ No

Comments: _____

K. CLOSING

1. Were there any comments or concerns? If yes, see Appendix A for instructions and details.

   ○ Yes ○ No

2. Were any CARs issued during this initial inspection? If yes, see Appendix B for instructions and details.

   ○ Yes ○ No

INITIAL INSPECTION OVERVIEW:

Company Representative Signature

Date:

Print Name:

Company

Inspector's Signature

Date:

Print Name:

Company

For IAPMO UES Staff Use Only

QA Inspection Documentation Reviewer:_____ Date: _____

APPENDIX A - COMMENTS and/or CONCERNS

Comments/Concerns (C/C) should be numbered sequentially. Details should be provided in the "Comments" blocks. Each C/C should be classified as a Comment or Concern depending on its immediacy. The relevant page or document from the Quality Control Manual should be cited, along with its revision date. Provide a reference to the requirement in the criteria (shown in the checklist above) or provide the corresponding item letters and numbers: (*Add sheets as necessary*.)

- **Concern** – A possible weakness in the quality system that should be addressed to avert possible future CARs.
- **Comment** – An opportunity for improvement.

C/C NO.	○ **Concern**	○ **Comment**	**Reference:**	
Quality Documentation (Doc. and Date):				

Comments:

C/C NO.	○ **Concern**	○ **Comment**	**Reference:**	
Quality Documentation (Doc. and Date):				

Comments:

C/C NO.	○ **Concern**	○ **Comment**	**Reference:**	
Quality Documentation (Doc. and Date):				

Comments:

APPENDIX B - CORRECTIVE ACTION REQUESTS (CARs)

CARs should be numbered sequentially and described in the "Comments" blocks provided below. CARs are issued for aspects of the observed quality control procedures that do not follow the approved QCM or that will likely result in a non-conforming, and therefore unrecognized product. Examples are: change of key raw materials, significantly different manufacturing process, different final product specifications, equipment out of calibration, changes to forms, inadequately trained personnel, etc. Provide a reference to the requirement in the criteria (shown in the checklist above; i.e. POV-xx) or provide the corresponding item letters and numbers. The relevant page or document from the Quality Control Manual should be cited, along with its revision date. (*Add sheets as necessary*.)

CARs shall be addressed within 30 days of the initial inspection. The manufacturer or report holder shall respond with a written report on the corrective actions taken and objective evidence of the action. Objective evidence could be in the form of revised documents, new documents, photographs, etc. Responses shall be submitted to the Inspector / Inspection Agency for review and transmittal to IAPMO UES. The CARs shall be resolved to the satisfaction of the IAPMO UES technical staff.

CAR NO.	**Reference:**	
Quality Documentation (Doc. and Date):		

Comments:

CAR NO.	**Reference:**	
Quality Documentation (Doc. and Date):		

Comments: