IAPMO UNIFORM EVALUATION SERVICE, LLC
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Form IR-1

SURVEILLANCE 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 inspection which is to verify conformance with the evaluation report or listing report and to ensure systems are in place to verify consistency of production with the data submitted in support of the evaluation or listing report. In order to do so 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. Inquire as to the readiness of the facility to undergo the inspection; confirm that the facility is operating in accordance with the latest approved quality control manual (QCM) and the product meets specifications (if the facility is not ready, re-scheduling the inspection should be considered.)

Complete the basic information identifying the product, the manufacturing facility, and the inspection agency on this page. Obtain a copy of the QCM and current/relevant evaluation report or listing for reference during the inspection. Discuss any changes to the report, the quality management system documentation, the manufacturing methods, and/or quality control procedures since the last factory inspection. Obtain copies of any changes to the quality documentation and of the revision log for review and approval by IAPMO UES. Inquire as to the product that is currently being produced, if any of the product being produced is for additional companies or masked report holders, and if there are any tests scheduled or sampling needed.

Check the record of the previous inspection to identify any corrective action requests (CARs) that were issued and, during the inspection, make sure that these corrected aspects of the quality management system continue to function adequately. If any of the previous CARs remain unresolved, take appropriate action for resolution. Make sure to review any special instructions concerning the inspection that may have been provided by IAPMO UES.

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

3 - Conduct an exit interview:

The inspector must complete the section titled “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 CARs that are

issued. Finally, the inspection report must be signed and dated by the inspector and by the manufacturing representative to acknowledge understanding of the issues.

Documenting the surveillance 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 continued 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 maintain recognition, Appendix B is provided to record Corrective Action Requests (CARs).

ES-010 Points of QC Verification (POV)

A. DOCUMENTATION

1. [POV – 1] a. Are there any changes to the Report Holder information or Manufacturer contact information?

☐ Yes ☐ No

b. If so are the changes consistent with what is shown in the current Evaluation Report and Quality Documentation?

☐ Yes ☐ No ☐ N/A

Comments: _____

2. [POV – 10] Does the product(s) manufactured remain as described in the current Evaluation Report and Quality Documentation:

☐ Yes ☐ No

Comments: _____

3. [POV – 4] Are the Quality Documentation and/or Quality Control Manual currently used during manufacturing consistent:

a. With the documentation from the last inspection?

☐ Yes ☐ No

b. And/or submitted to IAPMO UES?

☐ Yes ☐ No

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

Comments: _____

4. [POV – 3] Has there been a change to any key position descriptions and responsibilities or to the organizational chart?

☐ Yes ☐ No

(If yes, attach copy of new organizational chart and description of duties, along with an updated revision log)

Comments: _____

5. [POV – 12] Are the forms and records required by the quality system being completed correctly to maintain adequate traceability?

☐ Yes ☐ No

Comments: _____

6. [POV – 13] Complaints:

a. Have there been any client complaints recorded for the product?
☐ Yes ☐ No

b. If yes, have the appropriate actions been completed and documented?
☐ Yes ☐ No ☐ N/A

Comments: _____

B. MANUFACTURING PROCESS

1. [POV – 10a] Are the labels being installed in the correct location as required in the Quality Documentation?

☐ Yes ☐ No

1a. At a minimum do the labels display the information as noted in the Identification Section on each Evaluation Report covered by this inspection?

☐ Yes ☐ No

Comments: _____

[POV – 10a] Are the labels being controlled against misuse?
☐ Yes ☐ No

Comments: _____

[POV – 7] Is the production process (flowchart) that is represented in the approved quality control manual different than of the actual production flow and process?
☐ Yes ☐ No

Comments: _____

[POV – 7] Have the incoming (raw) materials changed since the last inspection?
☐ Yes ☐ No

Do the actual materials match the material specifications as those noted in the approved Quality Documentation?

☐ Yes ☐ No

Comments: _____

[POV – 7] Are the required test(s) and/or inspection(s) on the incoming materials being carried out as required by the approved Quality Documentation?
☐ Yes ☐ No

Comments: _____

[POV – 8 & 12] Are the In-Process Quality Control checks conducted during manufacturing as described in the approved Quality Documentation?
☐ Yes ☐ No

Comments: _____

[POV – 11] Are the non-conforming or non-compliant materials segregated as noted in the Quality Documentation?
☐ Yes ☐ No

Comments: _____

[POV – 9a] Are the measuring and testing equipment calibration up-to-date and being used adequately?
☐ Yes ☐ No ☐ N/A (if N/A, please comment below)

Are the approved calibration procedures being followed?
☐ Yes ☐ No ☐ N/A (if N/A, please comment below)

Comments: _____

[POV – 10] Are the final inspection(s) or test(s) being carried out, as described in the approved Quality Documentation prior to final approval?
☐ Yes ☐ No ☐ N/A (if N/A, please comment below)

Comments: _____

C. PRODUCTS

1. [POV – 10] Do the labeled product(s) meet the description(s), as described in the Evaluation Report and approved Quality Documentation?
☐ Yes ☐ No

Comments: _____

Do the specifications/assembly drawings meet the description(s), as described in the Evaluation Report and approved Quality Documentation?
☐ Yes ☐ No

Comments: _____

Do the manufacturing tolerances meet the description(s), as described in the Quality Documentation?
☐ Yes ☐ No

Comments: _____

D. 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 surveillance inspection? If yes, see Appendix B for instructions and details.

☐ Yes ☐ No

SURVEILLANCE INSPECTION OVERVIEW (Comments and Concerns to be noted in Appendix A/CARS in Appendix B):

Company Representative Signature

Date:

Print Name:

Company

Inspector 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** –Issues not related to product performance but determined to be a possible weakness in the quality system.
- **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, inadequately trained personnel, etc. Provide a reference to the requirement in the inspection report 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 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 Auditor / 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:		